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(Original Signature of Member)

107TH CONGRESS
2D SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

Mr. RANGEL (for himself, Mr. DINGELL, [insert names of additional cosponsors from attached list]) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for a voluntary medicare prescription medicine benefit, to provide greater access to affordable pharmaceuticals, to revise and improve payments to providers of services under the medicare program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCES IN ACT; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Rx Drug Benefit and Discount Act of 2002''.

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in title I of this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) BIPA; SECRETARY.—In this Act:

(1) BIPA.—The term ''BIPA'' means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554.

(2) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(d) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—PRESCRIPTION MEDICINE PROVISIONS

Subtitle A—MEDICARE PRESCRIPTION MEDICINE BENEFIT

SEC. 101. VOLUNTARY MEDICARE OUTPATIENT PRESCRIPTION MEDICINE PROGRAM.

(a) In General.—Title XVIII (42 U.S.C. 1395 et seq.) is amended—

(1) by redesignating section 1859 and part D as section 1858 and part E, respectively; and

(2) by inserting after part C the following new part:

"PART D—VOLUNTARY PRESCRIPTION MEDICINE BENEFIT FOR THE AGED AND DISABLED

"MEDICARE OUTPATIENT PRESCRIPTION MEDICINE BENEFIT

"SEC. 1859. Subject to the succeeding provisions of this part, the voluntary prescription medicine benefit program under this part provides the following:

"(1) PREMIUM.—The monthly premium is $25.

"(2) DEDUCTIBLE.—The annual deductible is $100.

"(3) COINSURANCE.—The coinsurance is 20 percent.

"(4) OUT-OF-POCKET LIMIT.—The annual limit on out-of-pocket spending on covered medicines is $2,000.

"NEGOTIATING FAIR PRICES WITH PHARMACEUTICAL MANUFACTURERS

"SEC. 1859A. (a) AUTHORITY TO NEGOTIATE PRICES WITH MANUFACTURERS.—The Secretary shall, consistent with the requirements of this part and the goals of providing quality care and containing costs under this part, negotiate contracts with manufacturers of covered outpatient prescription medicines that provide for the maximum prices that may be charged to individuals enrolled under this part by participating pharmacies for dispensing such medicines to such individuals.

"(b) PROMOTION OF BREAKTHROUGH MEDICINES.—In conducting negotiations with manufacturers under this part, the Secretary shall take into account the goal of promoting the development of breakthrough medicines (as defined in section 1859H(b)).

"CONTRACT AUTHORITY

"SEC. 1859B. (a) CONTRACT AUTHORITY.—

"(1) IN GENERAL.—The Secretary is responsible for the administration of this part and shall enter into contracts with appropriate pharmacy contractors on a national or regional basis to administer the benefits under this part.

"(2) PROCEDURES.—The Secretary shall establish procedures under which the Secretary—

"(A) accepts bids submitted by entities to serve as pharmacy contractors under this part in a region or on a national basis;

"(B) awards contracts to such contractors to administer benefits under this part to eligible beneficiaries in the region or on a national basis; and

"(C) provides for the termination (and nonrenewal) of a contract in the case of a contractor's failure to meet the requirements of the contract and this part.

"(3) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into contracts under this part.

"(4) TERMS AND CONDITIONS.—Such contracts shall have such terms and conditions as the Secretary shall specify and shall be for such terms (of at least 2 years, but not to exceed 5 years) as the Secretary shall specify consistent with this part.

"(5) USE OF PHARMACY CONTRACTORS IN PRICE NEGOTIATIONS.—Such contracts shall require the contractor involved to negotiate contracts with manufacturers that provide for maximum prices for covered outpatient prescription medicines that are lower than the maximum prices negotiated under section 1859A(a), if applicable. The price reductions shall be passed on to eligible beneficiaries and the Secretary shall hold the contractor accountable for meeting performance requirements with respect to price reductions and limiting price increases.

"(6) AREA FOR CONTRACTS.—

"(A) REGIONAL BASIS.—

"(i) IN GENERAL.—Except as provided in clause (ii) and subject to subparagraph (B), the contract entered into between the Secretary and a pharmacy contractor shall require the contractor to administer the benefits under this part in a region

determined by the Secretary under subparagraph (B) or on a national basis.

"(ii) PARTIAL REGIONAL BASIS.—

"(I) IN GENERAL.—If determined appropriate by the Secretary, the Secretary may permit the benefits to be administered in a partial region determined appropriate by the Secretary.

"(II) REQUIREMENTS.—If the Secretary permits administration pursuant to subclause (I), the Secretary shall ensure that the partial region in which administration is effected is no smaller than a State and is at least the size of the commercial service area of the contractor for that area.

"(B) DETERMINATION.—

"(i) IN GENERAL.—In determining regions for contracts under this part, the Secretary shall—

"(I) take into account the number of individuals enrolled under this part in an area in order to encourage participation by pharmacy contractors; and

"(II) ensure that there are at least 10 different regions in the United States.

"(ii) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of administrative areas under this paragraph shall not be subject to administrative or judicial review.

"(7) SUBMISSION OF BIDS.—

"(A) SUBMISSION.—

"(i) IN GENERAL.—Subject to subparagraph (B), each entity desiring to serve as a pharmacy contractor under this part in an area shall submit a bid with respect to such area to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

"(ii) BID THAT COVERS MULTIPLE AREAS.—The Secretary shall permit an entity to submit a single bid for multiple areas if the bid is applicable to all such areas.

"(B) REQUIRED INFORMATION.—The bids described in subparagraph (A) shall include—

"(i) a proposal for the estimated prices of covered outpatient prescription medicines and the projected annual increases in such prices, including the additional reduction in price negotiated below the Secretary's maximum price and differentials between preferred and nonpreferred prices, if applicable;

"(ii) a statement regarding the amount that the entity will charge the Secretary for administering the benefits under the contract;

"(iii) a statement regarding whether the entity will reduce the applicable coinsurance percentage pursuant to section 1859E(a)(1)(A)(ii) and if so, the amount of such reduction and how such reduction is tied to the performance requirements described in subsection (c)(4)(A)(ii);

"(iv) a detailed description of the performance requirements for which the administrative fee of the entity will be subject to risk pursuant to subsection (c)(4)(A)(ii);

"(v) a detailed description of access to pharmacy services provided by the entity, including information regarding whether the pharmacy contractor will use a preferred pharmacy network, and, if so, how the pharmacy contractor will ensure access to pharmacies that choose to be outside of that network, and whether there will be increased cost-sharing for beneficiaries if they obtain medicines at such pharmacies;

"(vi) a detailed description of the procedures and standards the entity will use for—

"(I) selecting preferred prescription medicines; and

"(II) determining when and how often the list of preferred prescription medicines should be modified;

"(vii) a detailed description of any ownership or shared financial interests with pharmaceutical manufacturers, pharmacies, and other entities involved in the administration or delivery of benefits under this part as proposed in the bid;

"(viii) a detailed description of the entity's estimated marketing and advertising expenditures related to enrolling and retaining eligible beneficiaries; and

"(ix) such other information that the Secretary determines is necessary in order to carry out this part, including information relating to the bidding process under this part.

The procedures under clause (vi) shall include the use of a pharmaceutical and therapeutics committee the members of which include practicing pharmacists.

"(8) AWARDING OF CONTRACTS.—

"(A) NUMBER OF CONTRACTS.—The Secretary shall, consistent with the requirements of this part and the goals of providing quality care and of containing costs under this part, award in a competitive manner at least 2 contracts to administer benefits under this part in each area specified under paragraph (6), unless only 1 pharmacy contractor submitting a bid meets the minimum standards specified under this part and by the Secretary.

"(B) DETERMINATION.—In determining which of the pharmacy contractors that submitted bids that meet the minimum standards specified under this part and by the Secretary to award a contract, the Secretary shall consider the comparative merits of each

bid, as determined on the basis of relevant factors, with respect to—

"(i) how well the contractor meets such minimum standards;

"(ii) the amount that the contractor will charge the Secretary for administering the benefits under the contract;

"(iii) the performance standards established under subsection (c)(2) and performance requirements for which the administrative fee of the entity will be subject to risk pursuant to subsection (c)(4)(A)(ii);

"(iv) the proposed negotiated prices of covered outpatient medicines and annual increases in such prices;

"(v) factors relating to benefits, quality and performance, beneficiary cost-sharing, and consumer satisfaction;

"(vi) past performance and prior experience of the contractor in administering a prescription medicine benefit program;

"(vii) effectiveness of the contractor in containing costs through pricing incentives and utilization management; and

"(viii) such other factors as the Secretary deems necessary to evaluate the merits of each bid.

"(C) EXCEPTION TO CONFLICT OF INTEREST RULES.—In awarding contracts with pharmacy contractors under this part, the Secretary may waive conflict of interest laws generally applicable to Federal acquisitions (subject to such safeguards as the Secretary may find necessary to impose) in circumstances where the Secretary finds that such waiver—

"(i) is not inconsistent with the—

"(I) purposes of the programs under this part; or

"(II) best interests of beneficiaries enrolled under this part; and

"(ii) permits a sufficient level of competition for such contracts, promotes efficiency of benefits administration, or otherwise serves the objectives of the program under this part.

"(D) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of the Secretary to award or not award a contract to a pharmacy contractor under this part shall not be subject to administrative or judicial review.

"(9) ACCESS TO BENEFITS IN CERTAIN AREAS.—

"(A) AREAS NOT COVERED BY CONTRACTS.—The Secretary shall develop procedures for the provision of covered outpatient prescription medicines under this part to each eligible beneficiary enrolled under this part that resides in an area that is not covered by any contract under this part.

"(B) BENEFICIARIES RESIDING IN DIFFERENT LOCATIONS.—The Secretary shall develop procedures to ensure that each eligible beneficiary enrolled under this part that resides in different areas in a year is provided the benefits under this part throughout the entire year.

"(b) QUALITY, FINANCIAL, AND OTHER STANDARDS AND PROGRAMS.—In consultation with appropriate pharmacy contractors, pharmacists, and health care professionals with expertise in prescribing, dispensing, and the appropriate use of prescription medicines, the Secretary shall establish standards and programs for the administration of this part to ensure appropriate prescribing, dispensing, and utilization of outpatient medicines under this part, to avoid adverse medicine reactions, and to continually reduce errors in the delivery of medically appropriate covered benefits. The Secretary shall not award a contract to a pharmacy contractor under this part unless the Secretary finds that the contractor agrees to comply with such standards and programs and other terms and conditions as the Secretary shall specify. The standards and programs under this

subsection shall be applied to any administrative agreements described in subsection (a) the Secretary enters into. Such standards and programs shall include the following:

"(1) ACCESS.—

"(A) IN GENERAL.—The pharmacy contractor shall ensure that covered outpatient prescription medicines are accessible and convenient to eligible beneficiaries enrolled under this part for whom benefits are administered by the pharmacy contractor, including by offering the services 24 hours a day and 7 days a week for emergencies.

"(B) ON-LINE REVIEW.—The pharmacy contractor shall provide for on-line prospective review available 24 hours a day and 7 days a week in order to evaluate each prescription for medicine therapy problems due to duplication, interaction, or incorrect dosage or duration of therapy.

"(C) GUARANTEED ACCESS TO MEDICINES IN RURAL AND HARD-TO-SERVE AREAS.—The Secretary shall ensure that all beneficiaries have guaranteed access to the full range of pharmaceuticals under this part, and shall give special attention to access, pharmacist counseling, and delivery in rural and hard-to-serve areas, including through the use of incentives such as bonus payments to retail pharmacists in rural areas and extra payments to the pharmacy contractor for the cost of rapid delivery of pharmaceuticals and any other actions necessary.

"(D) PREFERRED PHARMACY NETWORKS.—

"(i) IN GENERAL.—If a pharmacy contractor uses a preferred pharmacy network to deliver benefits under this part, such network shall meet minimum access standards established by the Secretary.

"(ii) STANDARDS.—In establishing standards under clause (i), the Secretary shall take into ac-

count reasonable distances to pharmacy services in both urban and rural areas.

''(E) ADHERENCE TO NEGOTIATED PRICES.—The pharmacy contractor shall have in place procedures to assure compliance of pharmacies with the requirements of subsection (d)(3)(C) (relating to adherence to negotiated prices).

''(F) CONTINUITY OF CARE.—

''(i) IN GENERAL.—The pharmacy contractor shall ensure that, in the case of an eligible beneficiary who loses coverage under this part with such entity under circumstances that would permit a special election period (as established by the Secretary under section 1859C(b)(3)), the contractor will continue to provide coverage under this part to such beneficiary until the beneficiary enrolls and receives such coverage with another pharmacy contractor under this part or, if eligible, with a Medicare+Choice organization.

''(ii) LIMITED PERIOD.—In no event shall a pharmacy contractor be required to provide the extended coverage required under clause (i) beyond the date which is 30 days after the coverage with such contractor would have terminated but for this subparagraph.

''(2) ENROLLEE GUIDELINES.—The pharmacy contractor shall, consistent with State law, apply guidelines for counseling enrollees regarding—

''(A) the proper use of covered outpatient prescription medicine: and

''(B) interactions and contra-indications.

''(3) EDUCATION.—The pharmacy contractor shall apply methods to identify and educate providers, pharmacists, and enrollees regarding—

''(A) instances or patterns concerning the unnecessary or inappropriate prescribing or dispensing of covered outpatient prescription medicines;

"(B) instances or patterns of substandard care;

"(C) potential adverse reactions to covered outpatient prescription medicines;

"(D) inappropriate use of antibiotics;

"(E) appropriate use of generic products; and

"(F) the importance of using covered outpatient prescription medicines in accordance with the instruction of prescribing providers.

"(4) COORDINATION.—The pharmacy contractor shall coordinate with State prescription medicine programs, other pharmacy contractors, pharmacies, and other relevant entities as necessary to ensure appropriate coordination of benefits with respect to enrolled individuals when such individual is traveling outside the home service area, and under such other circumstances as the Secretary may specify.

"(5) COST DATA.—

"(A) The pharmacy contractor shall make data on prescription medicine negotiated prices (including data on discounts) available to the Secretary.

"(B) The Secretary shall require, either directly or through a pharmacy contractor, that participating pharmacists, physicians, and manufacturers—

"(i) maintain their prescription medicine cost data (including data on discounts) in a form and manner specified by the Secretary;

"(ii) make such prescription medicine cost data available for review and audit by the Secretary; and

"(iii) certify that the prescription medicine cost data are current, accurate, and complete, and reflect all discounts obtained by the pharmacist or physician in the purchasing of covered outpatient prescription medicines.

Discounts referred to in subparagraphs (A) and (B) shall include all volume discounts, manufacturer rebates, prompt payment discounts, free goods, in-kind services, or any other thing of financial value provided explicitly or implic-

itly in exchange for the purchase of a covered outpatient prescription medicine.

''(6) REPORTING.—The pharmacy contractor shall provide the Secretary with periodic reports on—

''(A) the contractor's costs of administering this part;

''(B) utilization of benefits under this part;

''(C) marketing and advertising expenditures related to enrolling and retaining individuals under this part; and

''(D) grievances and appeals.

''(7) RECORDS AND AUDITS.—The pharmacy contractor shall maintain adequate records related to the administration of benefits under this part and afford the Secretary access to such records for auditing purposes.

''(8) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—The pharmacy contractor shall comply with requirements of section 1851(h) (relating to marketing material and application forms) with respect to this part in the same manner as such requirements apply under part C, except that the provisions of paragraph (4)(A) of such section shall not apply with respect to discounts or rebates provided in accordance with this part.

''(c) INCENTIVES FOR COST AND UTILIZATION MANAGEMENT AND QUALITY IMPROVEMENT.—

''(1) IN GENERAL.—The Secretary shall include in a contract awarded under subsection (b) with a pharmacy contractor such incentives for cost and utilization management and quality improvement as the Secretary may deem appropriate. The contract may provide financial or other incentives to encourage greater savings to the program under this part.

''(2) PERFORMANCE STANDARDS.—The Secretary shall provide for performance standards (which may include monetary bonuses if the standards are met and penalties if the standards are not met), including standards relating to the time taken to answer member and pharmacy inquir-

ies (written or by telephone), the accuracy of responses, claims processing accuracy, online system availability, appeal procedure turnaround time, system availability, the accuracy and timeliness of reports, and level of beneficiary satisfaction.

''(3) OTHER INCENTIVES.—Such incentives under this subsection may also include—

''(A) financial incentives under which savings derived from the substitution of generic and other preferred multi-source medicines in lieu of nongeneric and nonpreferred medicines are made available to pharmacy contractors, pharmacies, beneficiaries, and the Federal Medicare Prescription Medicine Trust Fund; and

''(B) any other incentive that the Secretary deems appropriate and likely to be effective in managing costs or utilization or improving quality that does not reduce the access of beneficiaries to medically necessary covered outpatient medicines.

''(4) REQUIREMENTS FOR PROCEDURES.—

''(A) IN GENERAL.—The Secretary shall establish procedures for making payments to each pharmacy contractor with a contract under this part for the administration of the benefits under this part. The procedures shall provide for the following:

''(i) ADMINISTRATIVE PAYMENT.—Payment of administrative fees for such administration.

''(ii) RISK REQUIREMENT.—An adjustment of a percentage (determined under subparagraph (B)) of the administrative fee payments made to a pharmacy contractor to ensure that the contractor, in administering the benefits under this part, pursues performance requirements established by the Secretary, including the following:

''(I) QUALITY SERVICE.—The contractor provides eligible beneficiaries for whom it administers benefits with quality services, as measured by such factors as sustained phar-

macy network access, timeliness and accuracy of service delivery in claims processing and card production, pharmacy and member service support access, and timely action with regard to appeals and current beneficiary service surveys.

"(II) QUALITY CLINICAL CARE.—The contractor provides such beneficiaries with quality clinical care, as measured by such factors as providing notification to such beneficiaries and to providers in order to prevent adverse drug reactions and reduce medication errors and specific clinical suggestions to improve health and patient and prescriber education as appropriate.

"(III) CONTROL OF MEDICARE COSTS.—The contractor contains costs under this part to the Federal Medicare Prescription Medicine Trust Fund and enrollees, as measured by generic substitution rates, price discounts, and other factors determined appropriate by the Secretary that do not reduce the access of beneficiaries to medically necessary covered outpatient prescription medicines.

"(B) PERCENTAGE OF PAYMENT TIED TO RISK.—

"(i) IN GENERAL.—Subject to clause (ii), the Secretary shall determine the percentage of the administrative payments to a pharmacy contractor that will be tied to the performance requirements described in subparagraph (A)(ii).

"(ii) LIMITATION ON RISK TO ENSURE PROGRAM STABILITY.—In order to provide for program stability, the Secretary may not establish a percentage to be adjusted under this paragraph at a level that jeopardizes the ability of a pharmacy contractor to administer the benefits under this part or administer such benefits in a quality manner.

"(C) RISK ADJUSTMENT OF PAYMENTS BASED ON ENROLLEES IN PLAN.—To the extent that a pharmacy contractor is at risk under this paragraph, the procedures established under this paragraph may include a methodology for risk adjusting the payments made to such contractor based on the differences in actuarial risk of different enrollees being served if the Secretary determines such adjustments to be necessary and appropriate.

"(d) AUTHORITY RELATING TO PHARMACY PARTICIPATION.—

"(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, a pharmacy contractor may establish consistent with this part conditions for the participation of pharmacies, including conditions relating to quality (including reduction of medical errors) and technology.

"(2) AGREEMENTS WITH PHARMACIES.—Each pharmacy contractor shall enter into a participation agreement with any pharmacy that meets the requirements of this subsection and section 1859E to furnish covered outpatient prescription medicines to individuals enrolled under this part.

"(3) TERMS OF AGREEMENT.—An agreement under this subsection shall include the following terms and conditions:

"(A) APPLICABLE REQUIREMENTS.—The pharmacy shall meet (and throughout the contract period continue to meet) all applicable Federal requirements and State and local licensing requirements.

"(B) ACCESS AND QUALITY STANDARDS.—The pharmacy shall comply with such standards as the Secretary (and such a pharmacy contractor) shall establish concerning the quality of, and enrolled individuals' access to, pharmacy services under this part. Such standards shall require the pharmacy—

"(i) not to refuse to dispense covered outpatient prescription medicines to any individual enrolled under this part;

"(ii) to keep patient records (including records on expenses) for all covered outpatient prescription medicines dispensed to such enrolled individuals;

"(iii) to submit information (in a manner specified by the Secretary to be necessary to administer this part) on all purchases of such medicines dispensed to such enrolled individuals; and

"(iv) to comply with periodic audits to assure compliance with the requirements of this part and the accuracy of information submitted.

"(C) ADHERENCE TO NEGOTIATED PRICES.—(i) The total charge for each medicine dispensed by the pharmacy to an enrolled individual under this part, without regard to whether the individual is financially responsible for any or all of such charge, shall not exceed the price negotiated under section 1859A(a) or, if lower, negotiated under subsection (a)(5) (or, if less, the retail price for the medicine involved) with respect to such medicine plus a reasonable dispensing fee determined contractually with the pharmacy contractor.

"(ii) The pharmacy does not charge (or collect from) an enrolled individual an amount that exceeds the individual's obligation (as determined in accordance with the provisions of this part) of the applicable price described in clause (i).

"(D) ADDITIONAL REQUIREMENTS.—The pharmacy shall meet such additional contract requirements as the applicable pharmacy contractor specifies under this section.

"(4) APPLICABILITY OF FRAUD AND ABUSE PROVISIONS.—The provisions of section 1128 through 1128C (relating to fraud and abuse) apply to pharmacies participating in the program under this part.

''ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

''SEC. 1859C. (a) ELIGIBILITY.—Each individual who is entitled to hospital insurance benefits under part A or is eligible to be enrolled in the medical insurance program under part B is eligible to enroll in accordance with this section for outpatient prescription medicine benefits under this part.

''(b) VOLUNTARY ENROLLMENT.—

''(1) IN GENERAL.—An individual may enroll under this part only in such manner and form as may be prescribed by regulations, and only during an enrollment period prescribed in or under this subsection.

''(2) INITIAL ENROLLMENT PERIOD.—

''(A) INDIVIDUALS CURRENTLY COVERED.—In the case of an individual who satisfies subsection (a) as of November 1, 2004, the initial general enrollment period shall begin on August 1, 2004, and shall end on March 1, 2005.

''(B) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who first satisfies subsection (a) on or after November 1, 2004, the individual's initial enrollment period shall begin on the first day of the third month before the month in which such individual first satisfies such paragraph and shall end seven months later. The Secretary shall apply rules similar to the rule described in the second sentence of section 1837(d).

''(3) SPECIAL ENROLLMENT PERIODS (WITHOUT PREMIUM PENALTY).—

''(A) EMPLOYER COVERAGE AT TIME OF INITIAL GENERAL ENROLLMENT PERIOD.—In the case of an individual who—

''(i) at the time the individual first satisfies subsection (a) is enrolled in a group health plan (including continuation coverage) that provides outpatient prescription medicine coverage by reason of the individual's (or the individual's spouse's) cur-

rent (or, in the case of continuation coverage, former) employment status, and

"(ii) has elected not to enroll (or to be deemed enrolled) under this subsection during the individual's initial enrollment period,

there shall be a special enrollment period of 6 months beginning with the first month that includes the date of the individual's (or individual's spouse's) retirement from or termination of current employment status with the employer that sponsors the plan, or, in the case of continuation coverage, that includes the date of termination of such coverage, or that includes the date the plan substantially terminates outpatient prescription medicine coverage.

"(B) DROPPING OF RETIREE PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who—

"(i) at the time the individual first satisfies subsection (a) is enrolled in a group health plan that provides outpatient prescription medicine coverage other than by reason of the individual's (or the individual's spouse's) current employment; and

"(ii) has elected not to enroll (or to be deemed enrolled) under this subsection during the individual's initial enrollment period,

there shall be a special enrollment period of 6 months beginning with the first month that includes the date that the plan substantially terminates outpatient prescription medicine coverage and ending 6 months later.

"(C) LOSS OF MEDICARE+CHOICE PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who is enrolled under part C in a Medicare+Choice plan that provides prescription medicine benefits, if such enrollment is terminated because of the termination or reduction in service area of the plan, there shall be a special enrollment period of 6 months beginning with the first month that includes the date that

such plan is terminated or such reduction occurs and ending 6 months later.

"(D) LOSS OF MEDICAID PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who—

"(i) satisfies subsection (a);

"(ii) loses eligibility for benefits (that include benefits for prescription medicine) under a State plan after having been enrolled (or determined to be eligible) for such benefits under such plan; and

"(iii) is not otherwise enrolled under this subsection at the time of such loss of eligibility,

there shall be a special enrollment period specified by the Secretary of not less than 6 months beginning with the first month that includes the date that the individual loses such eligibility.

"(4) LATE ENROLLMENT WITH PREMIUM PENALTY.—The Secretary shall permit an individual who satisfies subsection (a) to enroll other than during the initial enrollment period under paragraph (2) or a special enrollment period under paragraph (3). But, in the case of such an enrollment, the amount of the monthly premium of the individual is subject to an increase under section 1859C(e)(1).

"(5) INFORMATION.—

"(A) IN GENERAL.—The Secretary shall broadly distribute information to individuals who satisfy subsection (a) on the benefits provided under this part. The Secretary shall periodically make available information on the cost differentials to enrollees for the use of generic medicines and other medicines.

"(B) TOLL-FREE HOTLINE.—The Secretary shall maintain a toll-free telephone hotline (which may be a hotline already used by the Secretary under this title) for purposes of providing assistance to beneficiaries in the program under this part, including responding to questions concerning coverage, enrollment, benefits, grievances and appeals procedures, and other aspects of such program.

"(6) ENROLLEE DEFINED.—For purposes of this part, the term 'enrollee' means an individual enrolled for benefits under this part.

"(c) COVERAGE PERIOD.—

"(1) IN GENERAL.—The period during which an individual is entitled to benefits under this part (in this subsection referred to as the individual's 'coverage period') shall begin on such a date as the Secretary shall establish consistent with the type of coverage rules described in subsections (a) and (e) of section 1838, except that in no case shall a coverage period begin before January 1, 2005. No payments may be made under this part with respect to the expenses of an individual unless such expenses were incurred by such individual during a period which, with respect to the individual, is a coverage period.

"(2) TERMINATION.—The Secretary shall provide for the application of provisions under this subsection similar to the provisions in section 1838(b).

"(d) PROVISION OF BENEFITS TO MEDICARE+CHOICE ENROLLEES.—In the case of an individual who is enrolled under this part and is enrolled in a Medicare+Choice plan under part C, the individual shall be provided the benefits under this part through such plan and not through payment under this part.

"(e) LATE ENROLLMENT PENALTIES; PAYMENT OF PREMIUMS.—

"(1) LATE ENROLLMENT PENALTY.—

"(A) IN GENERAL.—In the case of a late enrollment described in subsection (b)(4), subject to the succeeding provisions of this paragraph, the Secretary shall establish procedures for increasing the amount of the monthly premium under this part applicable to such enrollee by an amount that the Secretary determines is actuarially sound for each such period.

"(B) PERIODS TAKEN INTO ACCOUNT.—For purposes of calculating any 12-month period under subparagraph (A), there shall be taken into account

months of lapsed coverage in a manner comparable to that applicable under the second sentence of section 1839(b).

"(C) PERIODS NOT TAKEN INTO ACCOUNT.—

"(i) IN GENERAL.—For purposes of calculating any 12-month period under subparagraph (A), subject to clause (ii), there shall not be taken into account months for which the enrollee can demonstrate that the enrollee was covered under a group health plan that provides coverage of the cost of prescription medicines whose actuarial value (as defined by the Secretary) to the enrollee equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription medicine benefit program under this part.

"(ii) APPLICATION.—This subparagraph shall only apply with respect to a coverage period the enrollment for which occurs before the end of the 60-day period that begins on the first day of the month which includes the date on which the plan terminates or reduces its service area (in a manner that results in termination of enrollment), ceases to provide, or reduces the value of the prescription medicine coverage under such plan to below the value of the coverage provided under the program under this part.

"(2) INCORPORATION OF PREMIUM PAYMENT AND GOVERNMENT CONTRIBUTIONS PROVISIONS.—The provisions of sections 1840 and 1844(a)(1) shall apply to enrollees under this part in the same manner as they apply to individuals 65 years of age or older enrolled under part B. For purposes of this subsection, any reference in a section referred to in a previous subsection to the Federal Supplementary Medical Insurance Trust Fund is deemed a reference to the Federal Medicare Prescription Medicine Trust Fund.

"(f) ELECTION OF PHARMACY CONTRACTOR TO ADMINISTER BENEFITS.—The Secretary shall establish a process whereby each individual enrolled under this part and residing in a region may elect the pharmacy contractor that will administer the benefits under this part with respect to the individual. Such process shall permit the individual to make an initial election and to change such an election on at least an annual basis and under such other circumstances as the Secretary shall specify.

"PROVISION OF, AND ENTITLEMENT TO, BENEFITS

"SEC. 1859D. (a) BENEFITS.—Subject to the succeeding provisions of this section, the benefits provided to an enrollee by the program under this part shall consist of the following:

"(1) COVERED OUTPATIENT PRESCRIPTION MEDICINE BENEFITS.—Entitlement to have payment made on the individual's behalf for covered outpatient prescription medicines.

"(2) LIMITATION ON COST-SHARING FOR PART B OUTPATIENT PRESCRIPTION MEDICINES.—

"(A) IN GENERAL.—Once an enrollee has incurred aggregate countable cost-sharing (as defined in subparagraph (B)) equal to the stop-loss limit specified in subsection (c)(4) for expenses in a year, entitlement to the elimination of cost-sharing otherwise applicable under part B for additional expenses incurred in the year for outpatient prescription medicines or biologicals for which payment is made under part B.

"(B) COUNTABLE COST-SHARING DEFINED.—For purposes of this part, the term 'countable cost-sharing' means—

"(i) out-of-pocket expenses for outpatient prescription medicines with respect to which benefits are payable under part B, and

"(ii) cost-sharing under subsections (c)(3)(B) and (c)(3)(C)(i).

"(b) COVERED OUTPATIENT PRESCRIPTION MEDICINE DEFINED.—

"(1) IN GENERAL.—Except as provided in paragraph (2), for purposes of this part the term 'covered outpatient prescription medicine' means any of the following products:

"(A) A medicine which may be dispensed only upon prescription, and—

"(i) which is approved for safety and effectiveness as a prescription medicine under section 505 of the Federal Food, Drug, and Cosmetic Act;

"(ii)(I) which was commercially used or sold in the United States before the date of enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a medicine, and (II) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

"(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a medicine, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such medicine under such section because the Secretary has determined that the medicine is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

"(B) A biological product which—

"(i) may only be dispensed upon prescription;

"(ii) is licensed under section 351 of the Public Health Service Act; and

"(iii) is produced at an establishment licensed under such section to produce such product.

"(C) Insulin approved under appropriate Federal law, and needles, syringes, and disposable pumps for the administration of such insulin.

"(D) A prescribed medicine or biological product that would meet the requirements of subparagraph (A) or (B) but that is available over-the-counter in addition to being available upon prescription, but only if the particular dosage form or strength prescribed and required for the individual is not available over-the-counter.

"(E) Smoking cessation agents (as specified by the Secretary).

"(2) EXCLUSION.—The term 'covered outpatient prescription medicine' does not include—

"(A) medicines or classes of medicines, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), as the Secretary may specify and does not include such other medicines, classes, and uses as the Secretary may specify consistent with the goals of providing quality care and containing costs under this part;

"(B) except as provided in paragraphs (1)(D) and (1)(E), any product which may be distributed to individuals without a prescription;

"(C) any product when furnished as part of, or as incident to, a diagnostic service or any other item or service for which payment may be made under this title; or

"(D) any product that is covered under part B of this title.

"(c) PAYMENT OF BENEFITS.—

"(1) COVERED OUTPATIENT PRESCRIPTION MEDICINES.—There shall be paid from the Federal Medicare Prescription Medicine Trust Fund, in the case of each enrollee who incurs expenses for medicines with respect to which benefits are payable under this part under subsection (a)(1), amounts equal to the sum of—

"(A) the price for which the medicine is made available under this part (consistent with sections 1859A and 1859B), reduced by any applicable cost-sharing under paragraphs (2) and (3); and

"(B) a reasonable dispensing fee.

The price under subparagraph (A) shall in no case exceed the retail price for the medicine involved.

"(2) DEDUCTIBLE.—The amount of payment under paragraph (1) for expenses incurred in a year, beginning with 2005, shall be reduced by an annual deductible equal to the amount specified in section 1859(2) (subject to adjustment under paragraph (8)). Only expenses for countable cost-sharing (as defined in subsection (a)(2)(B)) shall be taken into account in applying this paragraph.

"(3) COINSURANCE.—

"(A) IN GENERAL.—The amount of payment under paragraph (1) for expenses incurred in a year shall be further reduced (subject to the stop-loss limit under paragraph (4)) by coinsurance as provided under this paragraph.

"(B) PREFERRED MEDICINES.—The coinsurance under this paragraph in the case of a preferred medicine (including a medicine treated as a preferred medicine under paragraph (5)), is equal to 20 percent of the price applicable under paragraph (1)(A) (or such lower percentage as may be provided for under section 1859E(a)(1)(A)(ii)). In this part, the term 'preferred medicine' means, with respect to medicines classified

within a therapeutic class, those medicines which have been designated as a preferred medicine by the Secretary or the pharmacy contractor involved with respect to that class and (in the case of a nongeneric medicine) with respect to which a contract has been negotiated under this part.

''(C) NONPREFERRED MEDICINES.—The coinsurance under this paragraph in the case of a nonpreferred medicine that is not treated as a preferred medicine under paragraph (5) is equal to the sum of—

''(i) 20 percent of the price for lowest price preferred medicine that is within the same therapeutic class; and

''(ii) the amount by which—

''(I) the price at which the nonpreferred medicine is made available to the enrollee; exceeds

''(II) the price of such lowest price preferred medicine.

''(4) NO COINSURANCE ONCE OUT-OF-POCKET EXPENDITURES EQUAL STOP-LOSS LIMIT.—Once an enrollee has incurred aggregate countable cost-sharing under paragraph (3) (including cost-sharing under part B attributable to outpatient prescription drugs or biologicals) equal to the amount specified in section 1859(4) (subject to adjustment under paragraph (8)) for expenses in a year—

''(A) there shall be no coinsurance under paragraph (3) for additional expenses incurred in the year involved; and

''(B) there shall be no coinsurance under part B for additional expenses incurred in the year involved for outpatient prescription drugs and biologicals.

''(5) APPEALS RIGHTS RELATING TO COVERAGE OF NONPREFERRED MEDICINES.—

''(A) PROCEDURES REGARDING THE DETERMINATION OF MEDICINES THAT ARE MEDICALLY NECESSARY.—Each pharmacy contractor shall have in

place procedures on a case-by-case basis to treat a nonpreferred medicine as a preferred medicine under this part if the preferred medicine is determined to be not as effective for the enrollee or to have significant adverse effect on the enrollee. Such procedures shall require that such determinations are based on professional medical judgment, the medical condition of the enrollee, and other medical evidence.

''(B) PROCEDURES REGARDING DENIALS OF CARE.—Such contractor shall have in place procedures to ensure—

''(i) a timely internal review for resolution of denials of coverage (in whole or in part and including those regarding the coverage of nonpreferred medicines) in accordance with the medical exigencies of the case and a timely resolution of complaints, by enrollees in the plan, or by providers, pharmacists, and other individuals acting on behalf of each such enrollee (with the enrollee's consent) in accordance with requirements (as established by the Secretary) that are comparable to such requirements for Medicare+Choice organizations under part C;

''(ii) that the entity complies in a timely manner with requirements established by the Secretary that (I) provide for an external review by an independent entity selected by the Secretary of denials of coverage described in clause (i) not resolved in the favor of the beneficiary (or other complainant) under the process described in such clause and (II) are comparable to the external review requirements established for Medicare+Choice organizations under part C; and

''(iii) that enrollees are provided with information regarding the appeals procedures under this part at the time of enrollment with a pharmacy

contractor under this part and upon request thereafter.

"(6) TRANSFER OF FUNDS TO COVER COSTS OF PART B PRESCRIPTION MEDICINE CATASTROPHIC BENEFIT.—With respect to benefits described in subsection (a)(2), there shall transferred from the Federal Medicare Prescription Medicine Trust Fund to the Federal Supplementary Medical Insurance Trust Fund amounts equivalent to the elimination of cost-sharing described in such subsection.

"(7) PERMITTING APPLICATION UNDER PART B OF NEGOTIATED PRICES.—For purposes of making payment under part B for medicines that would be covered outpatient prescription medicines but for the exclusion under subparagraph (B) or (C) of subsection (b)(2), the Secretary may elect to apply the payment basis used for payment of covered outpatient prescription medicines under this part instead of the payment basis otherwise used under such part, if it results in a lower cost to the program.

"(8) INFLATION ADJUSTMENT.—

"(A) IN GENERAL.—With respect to expenses incurred in a year after 2005—

"(i) the deductible under paragraph (2) is equal to the deductible determined under such paragraph (or this subparagraph) for the previous year increased by the percentage increase in per capita program expenditures (as estimated in advance for the year involved under subparagraph (B)); and

"(ii) the stop-loss limit under paragraph (3) is equal to the stop-loss limit determined under such paragraph (or this subparagraph) for the previous year increased by such percentage increase.

The Secretary shall adjust such percentage increase in subsequent years to take into account misestimations made of the per capita program expenditures under clauses (i) and (ii) in previous years. Any increase

under this subparagraph that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

"(B) ESTIMATION OF INCREASE IN PER CAPITA PROGRAM EXPENDITURES.—The Secretary shall before the beginning of each year (beginning with 2006) estimate the percentage increase in average per capita aggregate expenditures from the Federal Medicare Prescription Medicine Trust Fund for the year involved compared to the previous year.

"(C) RECONCILIATION.—The Secretary shall also compute (beginning with 2007) the actual percentage increase in such aggregate expenditures in order to provide for reconciliation of deductibles, stop-loss limits, and premiums under the second sentence of subparagraph (A) and under section 1859D(d)(2).

"(d) AMOUNT OF PREMIUMS.—

"(1) MONTHLY PREMIUM RATE IN 2005.—The monthly premium rate in 2005 for prescription medicine benefits under this part is the amount specified in section 1859(1).

"(2) INFLATION ADJUSTMENT FOR SUBSEQUENT YEARS.—The monthly premium rate for a year after 2005 for prescription medicine benefits under this part is equal to the monthly premium rate for the previous year under this subsection increased by the percentage increase in per capita program expenditures (as estimated in advance for the year involved under subsection (c)(8)(B)). The Secretary shall adjust such percentage in subsequent years to take into account misestimations made of the per capita program expenditures under the previous sentence in previous years. Any increase under this paragraph that is not a multiple of $1 shall be rounded to the nearest multiple of $1.

"ADMINISTRATION; QUALITY ASSURANCE

"SEC. 1859E. (a) RULES RELATING TO PROVISION OF BENEFITS.—

"(1) PROVISION OF BENEFITS.—

"(A) IN GENERAL.—In providing benefits under this part, the Secretary (directly or through the contracts with pharmacy contractors) shall employ mechanisms to provide benefits appropriately and efficiently, and those mechanisms may include—

"(i) the use of—

"(I) price negotiations (consistent with subsection (b));

"(II) reduced coinsurance (below 20 percent) to encourage the utilization of appropriate preferred medicines; and

"(III) methods to reduce medication errors and encourage appropriate use of medications; and

"(ii) permitting pharmacy contractors, as approved by the Secretary, to make exceptions to section 1859D(c)(3)(C) (relating to cost-sharing for non-preferred medicines) to secure best prices for enrollees so long as the payment amount under section 1859D(c)(1) does not equal zero.

"(B) CONSTRUCTION.—Nothing in this subsection shall be construed to prevent the Secretary (directly or through the contracts with pharmacy contractors) from using incentives to encourage enrollees to select generic or other cost-effective medicines, so long as—

"(i) such incentives are designed not to result in any increase in the aggregate expenditures under the Federal Medicare Prescription Medicine Trust Fund; and

"(ii) a beneficiary's coinsurance shall be no greater than 20 percent in the case of a preferred medicine (including a nonpreferred medicine treated as a preferred medicine under section 1859D(c)(5)).

"(2) CONSTRUCTION.—Nothing in this part shall preclude the Secretary or a pharmacy contractor from—

"(A) educating prescribing providers, pharmacists, and enrollees about medical and cost benefits of preferred medicines;

"(B) requesting prescribing providers to consider a preferred medicine prior to dispensing of a nonpreferred medicine, as long as such request does not unduly delay the provision of the medicine;

"(C) using mechanisms to encourage enrollees under this part to select cost-effective medicines or less costly means of receiving or administering medicines, including the use of therapeutic interchange programs, disease management programs, and notification to the beneficiary that a more affordable generic medicine equivalent was not selected by the prescribing provider and a statement of the lost cost savings to the beneficiary;

"(D) using price negotiations to achieve reduced prices on covered outpatient prescription medicines, including new medicines, medicines for which there are few therapeutic alternatives, and medicines of particular clinical importance to individuals enrolled under this part; and

"(E) utilizing information on medicine prices of OECD countries and of other payors in the United States in the negotiation of prices under this part.

"(b) PRICE NEGOTIATIONS PROCESS.—

"(1) REQUIREMENTS WITH RESPECT TO PREFERRED MEDICINES.—Negotiations of contracts with manufacturers with respect to covered outpatient prescription medicines under this part shall be conducted in a manner so that—

"(A) there is at least a contract for a medicine within each therapeutic class (as defined by the Secretary in consultation with such Medicare Prescription Medicine Advisory Committee);

"(B) if there is more than 1 medicine available in a therapeutic class, there are contracts for at least 2 medicines within such class unless determined clinically

inappropriate in accordance with standards established by the Secretary; and

"(C) if there are more than 2 medicines available in a therapeutic class, there is a contract for at least 2 medicines within such class and a contract for generic medicine substitute if available unless determined clinically inappropriate in accordance with standards established by the Secretary.

"(2) ESTABLISHMENT OF THERAPEUTIC CLASSES.—The Secretary, in consultation with the Medicare Prescription Medicine Advisory Committee (established under section 1859H), shall establish for purposes of this part therapeutic classes and assign to such classes covered outpatient prescription medicines.

"(3) DISCLOSURE CONCERNING PREFERRED MEDICINES.—The Secretary shall provide, through pharmacy contractors or otherwise, for—

"(A) disclosure to current and prospective enrollees and to participating providers and pharmacies in each service area a list of the preferred medicines and differences in applicable cost-sharing between such medicines and nonpreferred medicines; and

"(B) advance disclosure to current enrollees and to participating providers and pharmacies in each service area of changes to any such list of preferred medicines and differences in applicable cost-sharing.

"(4) NO REVIEW.—The Secretary's establishment of therapeutic classes and the assignment of medicines to such classes and the Secretary's determination of what is a breakthrough medicine are not subject to administrative or judicial review.

"(c) CONFIDENTIALITY.—The Secretary shall ensure that the confidentiality of individually identifiable health information relating to the provision of benefits under this part is protected, consistent with the standards for the privacy of such information promulgated by the Secretary under the Health Insurance Portability and Accountability Act of 1996, or any sub-

sequent comprehensive and more protective set of confidentiality standards enacted into law or promulgated by the Secretary. Nothing in this subsection shall be construed as preventing the coordination of data with a State prescription medicine program so long as such program has in place confidentiality standards that are equal to or exceed the standards used by the Secretary.

''(d) FRAUD AND ABUSE SAFEGUARDS.—The Secretary, through the Office of the Inspector General, is authorized and directed to issue regulations establishing appropriate safeguards to prevent fraud and abuse under this part. Such safeguards, at a minimum, should include compliance programs, certification data, audits, and recordkeeping practices. In developing such regulations, the Secretary shall consult with the Attorney General and other law enforcement and regulatory agencies.

''FEDERAL MEDICARE PRESCRIPTION MEDICINE TRUST FUND

''SEC. 1859F. (a) ESTABLISHMENT.—There is hereby created on the books of the Treasury of the United States a trust fund to be known as the 'Federal Medicare Prescription Medicine Trust Fund' (in this section referred to as the 'Trust Fund'). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), and such amounts as may be deposited in, or appropriated to, such fund as provided in this part.

''(b) APPLICATION OF SMI TRUST FUND PROVISIONS.—The provisions of subsections (b) through (i) of section 1841 shall apply to this part and the Trust Fund in the same manner as they apply to part B and the Federal Supplementary Medical Insurance Trust Fund, respectively.

''COMPENSATION FOR EMPLOYERS COVERING RETIREE MEDICINE COSTS

''SEC. 1859G. (a) IN GENERAL.—In the case of an individual who is eligible to be enrolled under this part and is a participant or beneficiary under a group health plan that provides outpatient prescription medicine coverage to retirees the actuarial value of which is not less than the actuarial value of

the coverage provided under this part, the Secretary shall make payments to such plan subject to the provisions of this section. Such payments shall be treated as payments under this part for purposes of sections 1859F and 1859C(e)(2). In applying the previous sentence with respect to section 1859C(e)(2), the amount of the Government contribution referred to in section 1844(a)(1)(A) is deemed to be equal to the aggregate amount of the payments made under this section.

"(b) REQUIREMENTS.—To receive payment under this section, a group health plan shall comply with the following requirements:

"(1) COMPLIANCE WITH REQUIREMENTS.—The group health plan shall comply with the requirements of this Act and other reasonable, necessary, and related requirements that are needed to administer this section, as determined by the Secretary.

"(2) ANNUAL ASSURANCES AND NOTICE BEFORE TERMINATION.—The sponsor of the plan shall—

"(A) annually attest, and provide such assurances as the Secretary may require, that the coverage offered under the group health plan meets the requirements of this section and will continue to meet such requirements for the duration of the sponsor's participation in the program under this section; and

"(B) guarantee that it will give notice to the Secretary and covered enrollees—

"(i) at least 120 days before terminating its plan, and

"(ii) immediately upon determining that the actuarial value of the prescription medicine benefit under the plan falls below the actuarial value required under subsection (a).

"(3) BENEFICIARY INFORMATION.—The sponsor of the plan shall report to the Secretary, for each calendar quarter for which it seeks a payment under this section, the names and social security numbers of all enrollees described in subsection (a) covered under such plan during such

quarter and the dates (if less than the full quarter) during which each such individual was covered.

"(4) AUDITS.—The sponsor or plan seeking payment under this section shall agree to maintain, and to afford the Secretary access to, such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription medicine coverage, the accuracy of payments made, and such other matters as may be appropriate.

"(c) PAYMENT.—

"(1) IN GENERAL.—The sponsor of a group health plan that meets the requirements of subsection (b) with respect to a quarter in a calendar year shall be entitled to have payment made on a quarterly basis of the amount specified in paragraph (2) for each individual described in subsection (a) who during the quarter is covered under the plan and was not enrolled in the insurance program under this part.

"(2) AMOUNT OF PAYMENT.—

"(A) IN GENERAL.—The amount of the payment for a quarter shall approximate, for each such covered individual, ⅔ of the sum of the monthly Government contribution amounts (computed under subparagraph (B)) for each of the 3 months in the quarter.

"(B) COMPUTATION OF MONTHLY GOVERNMENT CONTRIBUTION AMOUNT.—For purposes of subparagraph (A), the monthly Government contribution amount for a month in a year is equal to the amount by which—

"(i) 1/12 of the average per capita aggregate expenditures, as estimated under section 1859D(c)(8) for the year involved; exceeds

"(ii) the monthly premium rate under section 1859D(d) for the month involved.

''MEDICARE PRESCRIPTION MEDICINE ADVISORY COMMITTEE

''SEC. 1859H. (a) ESTABLISHMENT OF COMMITTEE.—There is established a Medicare Prescription Medicine Advisory Committee (in this section referred to as the 'Committee').

''(b) FUNCTIONS OF COMMITTEE.—The Committee shall advise the Secretary on policies related to—

''(1) the development of guidelines for the implementation and administration of the outpatient prescription medicine benefit program under this part; and

''(2) the development of—

''(A) standards required of pharmacy contractors under section 1859D(c)(5) for determining if a medicine is as effective for an enrollee or has a significant adverse effect on an enrollee under this part;

''(B) standards for—

''(i) defining therapeutic classes;

''(ii) adding new therapeutic classes;

''(iii) assigning to such classes covered outpatient prescription medicines; and

''(iv) identifying breakthrough medicines;

''(C) procedures to evaluate the bids submitted by pharmacy contractors under this part;

''(D) procedures for negotiations, and standards for entering into contracts, with manufacturers, including identifying medicines or classes of medicines where Secretarial negotiation is most likely to yield savings under this part significantly above those that which could be achieved by a pharmacy contractor; and

''(E) procedures to ensure that pharmacy contractors with a contract under this part are in compliance with the requirements under this part.

For purposes of this part, a medicine is a 'breakthrough medicine' if the Secretary, in consultation with the Committee, determines it is a new product that will make a significant and major improvement by reducing physical or mental illness, reducing mortality, or reducing disability, and that no other product is available to beneficiaries that achieves similar results

for the same condition. The Committee may consider cost-effectiveness in establishing standards for defining therapeutic classes and assigning drugs to such classes under subparagraph (B).

"(c) STRUCTURE AND MEMBERSHIP OF THE COMMITTEE.—

"(1) STRUCTURE.—The Committee shall be composed of 19 members who shall be appointed by the Secretary.

"(2) MEMBERSHIP.—

"(A) IN GENERAL.—The members of the Committee shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education, experience, and attainments, exceptionally qualified to perform the duties of members of the Committee.

"(B) SPECIFIC MEMBERS.—Of the members appointed under paragraph (1)—

"(i) 5 shall be chosen to represent practicing physicians, 2 of whom shall be gerontologists;

"(ii) 2 shall be chosen to represent practicing nurse practitioners;

"(iii) 4 shall be chosen to represent practicing pharmacists;

"(iv) 1 shall be chosen to represent the Centers for Medicare & Medicaid Services;

"(v) 4 shall be chosen to represent actuaries, pharmacoeconomists, researchers, and other appropriate experts;

"(vi) 1 shall be chosen to represent emerging medicine technologies;

"(vii) 1 shall be chosen to represent the Food and Drug Administration; and

"(viii) 1 shall be chosen to represent individuals enrolled under this part.

"(d) TERMS OF APPOINTMENT.—Each member of the Committee shall serve for a term determined appropriate by the

Secretary. The terms of service of the members initially appointed shall begin on January 1, 2004.

''(e) CHAIRPERSON.—The Secretary shall designate a member of the Committee as Chairperson. The term as Chairperson shall be for a 1-year period.

''(f) COMMITTEE PERSONNEL MATTERS.—

''(1) MEMBERS.—

''(A) COMPENSATION.—Each member of the Committee who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Committee. All members of the Committee who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

''(B) TRAVEL EXPENSES.—The members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Committee.

''(2) STAFF.—The Committee may appoint such personnel as the Committee considers appropriate.

''(g) OPERATION OF THE COMMITTEE.—

''(1) MEETINGS.—The Committee shall meet at the call of the Chairperson (after consultation with the other members of the Committee) not less often than quarterly to consider a specific agenda of issues, as determined by the Chairperson after such consultation.

''(2) QUORUM.—Ten members of the Committee shall constitute a quorum for purposes of conducting business.

''(h) FEDERAL ADVISORY COMMITTEE ACT.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Committee.

''(i) TRANSFER OF PERSONNEL, RESOURCES, AND ASSETS.—For purposes of carrying out its duties, the Secretary and the Committee may provide for the transfer to the Committee of such civil service personnel in the employ of the Department of Health and Human Services (including the Centers for Medicare & Medicaid Services), and such resources and assets of the Department used in carrying out this title, as the Committee requires.

''(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out the purposes of this section.''.

(b) APPLICATION OF GENERAL EXCLUSIONS FROM COVERAGE.—

(1) APPLICATION TO PART D.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended in the matter preceding paragraph (1) by striking ''part A or part B'' and inserting ''part A, B, or D''.

(2) PRESCRIPTION MEDICINES NOT EXCLUDED FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is amended—

(A) in subparagraph (H), by striking ''and'' at the end;

(B) in subparagraph (I), by striking the semicolon at the end and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(J) in the case of prescription medicines covered under part D, which are not prescribed in accordance with such part;''.

(c) CONFORMING AMENDMENTS.—(1) Part C of title XVIII is amended—

(A) in section 1851(a)(2)(B) (42 U.S.C. 1395w–21(a)(2)(B)), by striking ''1859(b)(3)'' and inserting ''1858(b)(3)'';

(B) in section 1851(a)(2)(C) (42 U.S.C. 1395w–21(a)(2)(C)), by striking ''1859(b)(2)'' and inserting ''1858(b)(2)'';

(C) in section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)), by striking ''1859(b)(3)'' and inserting ''1858(b)(3)'';

(D) in section 1852(a)(3)(B)(ii) (42 U.S.C. 1395w–22(a)(3)(B)(ii)), by striking ''1859(b)(2)(B)'' and inserting ''1858(b)(2)(B)'';

(E) in section 1853(a)(1)(A) (42 U.S.C. 1395w–23(a)(1)(A)), by striking ''1859(e)(4)'' and inserting ''1858(e)(4)''; and

(F) in section 1853(a)(3)(D) (42 U.S.C. 1395w–23(a)(3)(D)), by striking ''1859(e)(4)'' and inserting ''1858(e)(4)''.

(2) Section 1171(a)(5)(D) (42 U.S.C. 1320d(a)(5)(D)) is amended by striking ''or (C)'' and inserting ''(C), or (D)''.

SEC. 102. PROVISION OF MEDICARE OUTPATIENT PRESCRIPTION MEDICINE COVERAGE UNDER THE MEDICARE+CHOICE PROGRAM.

(a) REQUIRING AVAILABILITY OF AN ACTUARIALLY EQUIVALENT PRESCRIPTION MEDICINE BENEFIT.—Section 1851 (42 U.S.C. 1395w–21) is amended by adding at the end the following new subsection:

''(j) AVAILABILITY OF PRESCRIPTION MEDICINE BENEFITS.—

''(1) IN GENERAL.—Notwithstanding any other provision of this part, each Medicare+Choice organization that makes available a Medicare+Choice plan described in section 1851(a)(2)(A) shall make available such a plan that offers coverage of covered outpatient prescription medicines that is at least actuarially equivalent to the benefits provided under part D. Information respecting such benefits shall be made available in the same manner as information on other benefits provided under this part is made available. Nothing in this paragraph shall be construed as re-

quiring the offering of such coverage separate from coverage that includes benefits under parts A and B.

''(2) TREATMENT OF PRESCRIPTION MEDICINE ENROLLEES.—In the case of a Medicare+Choice eligible individual who is enrolled under part D, the benefits described in paragraph (1) shall be treated in the same manner as benefits described in part B for purposes of coverage and payment and any reference in this part to the Federal Supplementary Medical Insurance Trust Fund shall be deemed, with respect to such benefits, to be a reference to the Federal Medicare Prescription Medicine Trust Fund.''.

(b) APPLICATION OF QUALITY STANDARDS.—Section 1852(e)(2)(A) (42 U.S.C. 1395w–22(e)(2)(A)) is amended—

(1) by striking ''and'' at the end of clause (xi);

(2) by striking the period at the end of clause (xii) and inserting '', and''; and

(3) by adding at the end the following new clause:

''(xiii) comply with the standards, and apply the programs, under section 1859B(b) for covered outpatient prescription medicines under the plan.''.

(c) PAYMENT SEPARATE FROM PAYMENT FOR PART A AND B BENEFITS.—Section 1853 (42 U.S.C. 1395w–23) is amended—

(1) in subsection (a)(1)(A), by striking ''and (i)'' and inserting ''(i), and (j)''; and

(2) by adding at the end the following new subsection:

''(j) PAYMENT FOR PRESCRIPTION MEDICINE COVERAGE OPTION.—

''(1) IN GENERAL.—In the case of a Medicare+Choice plan that provides prescription medicine benefits described in section 1851(j)(1), the amount of payment otherwise made to the Medicare+Choice organization offering the plan shall be increased by the amount described in paragraph (2). Such payments shall be made in the same manner and time as the amount otherwise paid, but such amount shall be payable from the Federal Medicare Prescription Medicine Trust Fund.

''(2) AMOUNT.—The amount described in this paragraph is the monthly Government contribution amount computed under section 1859G(c)(2)(B), but subject to adjustment under paragraph (3). Such amount shall be uniform geographically and shall not vary based on the Medicare+Choice payment area involved.

''(3) RISK ADJUSTMENT.—The Secretary shall establish a methodology for the adjustment of the payment amount under this subsection in a manner that takes into account the relative risks for use of outpatient prescription medicines by Medicare+Choice enrollees. Such methodology shall be designed in a manner so that the total payments under this title (including part D) are not changed as a result of the application of such methodology.''.

(d) SEPARATE APPLICATION OF ADJUSTED COMMUNITY RATE (ACR).—Section 1854 (42 U.S.C. 1395w–24) is amended by adding at the end the following:

''(i) APPLICATION TO PRESCRIPTION MEDICINE COVERAGE.—The Secretary shall apply the previous provisions of this section (including the computation of the adjusted community rate) separately with respect to prescription medicine benefits described in section 1851(j)(1).''.

(f) CONFORMING AMENDMENTS.—

(1) Section 1851 (42 U.S.C. 1395w–21) is amended—

(A) in subsection (a)(1)(A), by striking ''parts A and B'' and inserting ''parts A, B, and D''; and

(B) in subsection (i) by inserting ''(and, if applicable, part D)'' after ''parts A and B''.

(2) Section 1852(a)(1)(A) (42 U.S.C. 1395w–22(a)(1)(A)) is amended by inserting ''(and under part D to individuals also enrolled under such part)'' after ''parts A and B''.

(3) Section 1852(d)(1) (42 U.S.C. 1395w–22(d)(1)) is amended—

(A) by striking ''and'' at the end of subparagraph (D);

(B) by striking the period at the end of subparagraph (E) and inserting ''; and''; and

(C) by adding at the end the following:

''(F) the plan for part D benefits guarantees coverage of any specifically named prescription medicine for an enrollee to the extent that it would be required to be covered under part D.

In carrying out subparagraph (F), a Medicare+Choice organization has the same authority to enter into contracts with respect to coverage of preferred medicines as the Secretary has under part D, but subject to an independent contractor appeal or other appeal process that would be applicable to determinations by such a pharmacy contractor consistent with section 1859D(c)(5).''.

(e) LIMITATION ON COST-SHARING.—Section 1854(e) (42 U.S.C. 1395w–24(e)) is amended by adding at the end the following new paragraph:

''(5) LIMITATION ON COST-SHARING.—In no event may a Medicare+Choice organization include a requirement that an enrollee pay cost-sharing in excess of the cost-sharing otherwise permitted under part D.''.

SEC. 103. MEDIGAP REVISIONS.

(a) REQUIRED COVERAGE OF COVERED OUTPATIENT PRESCRIPTION MEDICINES.—Section 1882(p)(2)(B) (42 U.S.C. 1395ss(p)(2)(B)) is amended by inserting before ''and'' at the end the following: ''including a requirement that an appropriate number of policies provide coverage of medicines which complements but does not duplicate the medicine benefits that beneficiaries are otherwise eligible for benefits under part D of this title (with the Secretary and the National Association of Insurance Commissioners determining the appropriate level of medicine benefits that each benefit package must provide and ensuring that policies providing such coverage are affordable for beneficiaries;''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on January 1, 2005.

(c) TRANSITION PROVISIONS.—

(1) IN GENERAL.—If the Secretary of Health and Human Services identifies a State as requiring a change to its statutes or regulations to conform its regulatory program to the amendments made by this section, the State regulatory program shall not be considered to be out of compliance with the requirements of section 1882 of the Social Security Act due solely to failure to make such change until the date specified in paragraph (4).

(2) NAIC STANDARDS.—If, within 9 months after the date of enactment of this Act, the National Association of Insurance Commissioners (in this subsection referred to as the ''NAIC'') modifies its NAIC Model Regulation relating to section 1882 of the Social Security Act (referred to in such section as the 1991 NAIC Model Regulation, as subsequently modified) to conform to the amendments made by this section, such revised regulation incorporating the modifications shall be considered to be the applicable NAIC model regulation (including the revised NAIC model regulation and the 1991 NAIC Model Regulation) for the purposes of such section.

(3) SECRETARY STANDARDS.—If the NAIC does not make the modifications described in paragraph (2) within the period specified in such paragraph, the Secretary of Health and Human Services shall make the modifications described in such paragraph and such revised regulation incorporating the modifications shall be considered to be the appropriate regulation for the purposes of such section.

(4) DATE SPECIFIED.—

(A) IN GENERAL.—Subject to subparagraph (B), the date specified in this paragraph for a State is the earlier of—

(i) the date the State changes its statutes or regulations to conform its regulatory program to the changes made by this section; or

(ii) 1 year after the date the NAIC or the Secretary first makes the modifications under paragraph (2) or (3), respectively.

(B) ADDITIONAL LEGISLATIVE ACTION REQUIRED.—In the case of a State which the Secretary identifies as—

(i) requiring State legislation (other than legislation appropriating funds) to conform its regulatory program to the changes made in this section; but

(ii) having a legislature which is not scheduled to meet in 2003 in a legislative session in which such legislation may be considered;

the date specified in this paragraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after January 1, 2003. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

SEC. 104. TRANSITIONAL ASSISTANCE FOR LOW INCOME BENEFICIARIES.

(a) QMB COVERAGE OF PREMIUMS AND COST-SHARING.—Section 1905(p)(3) (42 U.S.C. 1396d(p)(3)) is amended—

(1) in subparagraph (A)—

(A) by striking ''and'' at the end of clause (i),

(B) by adding ''and'' at the end of clause (ii), and

(C) by adding at the end the following new clause:

''(iii) premiums under section 1859D(d).'';

(2) in subparagraph (B), by inserting ''and section 1859D(c)(3)(B) and 1859D(c)(3)(C)(i)'' after ''1813''; and

(3) in subparagraph (C), by striking ''and section 1833(b)'' and inserting '', section 1833(b), and section 1859D(c)(2)''.

(b) EXPANDED SLMB ELIGIBILITY.—Section 1902(a)(10)(E) (42 U.S.C. 1396a(a)(10)(E)) is amended—

(1) by striking ''and'' at the end of clause (iii);

(2) by adding ''and'' at the end of clause (iv); and

(3) by adding at the end the following new clause:

''(v)(I) for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(iii) and medicare cost-sharing described in section 1905(p)(3)(B) and section 1905(p)(3)(C) but only insofar as it relates to benefits provided under part D of title XVIII, subject to section 1905(p)(4), for individuals (other than qualified medicare beneficiaries) who are enrolled under part D of title XVIII and are described in section 1905(p)(1)(B) or would be so described but for the fact that their income exceeds 100 percent, but is less than 150 percent, of the official poverty line (referred to in such section) for a family of the size involved;

''(II) subject to section 1905(p)(4), for individuals (other than qualified medicare beneficiaries and individuals described in subclause (I)) who are enrolled under part D of title XVIII and would be described in section 1905(p)(1)(B) but for the fact that their income exceeds 150 percent, but is less than 175 percent, of the official poverty line (referred to in such section) for a family of the size involved, for making medical assistance available for medicare cost-sharing described in section 1905(p)(3)(A)(iii) and medicare cost-sharing described in section 1905(p)(3)(B) and section 1905(p)(3)(C) but only insofar as it relates to benefits provided under part D of title XVIII, and the assistance for medicare cost-sharing described in section 1905(p)(3)(A)(iii) is reduced (on a sliding scale based on income) from 100 percent to 0 percent as the income increases from 150 percent to 175 percent of such poverty line;''.

(c) FEDERAL FINANCING.—The third sentence of section 1905(b) (42 U.S.C. 1396d(b)) is amended by inserting before the period at the end the following: ''and with respect to amounts expended that are attributable to section

1902(a)(10)(E)(v) (other than for individuals described in section 1905(p)(1)(B))''.

(d) TREATMENT OF TERRITORIES.—

(1) IN GENERAL.—Section 1905(p) (42 U.S.C. 1396d(p)) is amended—

(A) by redesignating paragraphs (5) and (6) as paragraphs (6) and (7), respectively; and

(B) by inserting after paragraph (4) the following new paragraph:

''(5)(A) In the case of a State, other than the 50 States and the District of Columbia—

''(i) the provisions of paragraph (3) insofar as they relate to section 1859D and the provisions of section 1902(a)(10)(E)(v) shall not apply to residents of such State; and

''(ii) if the State establishes a plan described in subparagraph (B) (for providing medical assistance with respect to the provision of prescription medicines to medicare beneficiaries), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount specified in subparagraph (C).

''(B) The plan described in this subparagraph is a plan that—

''(i) provides medical assistance with respect to the provision of covered outpatient medicines (as defined in section 1859D(b)) to low-income medicare beneficiaries; and

''(ii) assures that additional amounts received by the State that are attributable to the operation of this paragraph are used only for such assistance.

''(C)(i) The amount specified in this subparagraph for a State for a year is equal to the product of—

''(I) the aggregate amount specified in clause (ii); and

''(II) the amount specified in section 1108(g)(1) for that State, divided by the sum of the amounts specified in such section for all such States.

''(ii) The aggregate amount specified in this clause for—

''(I) 2005, is equal to $25,000,000; or

''(II) a subsequent year, is equal to the aggregate amount specified in this clause for the previous year increased by annual percentage increase specified in section 1859D(c)(8)(B) for the year involved.

''(D) The Secretary shall submit to Congress a report on the application of this paragraph and may include in the report such recommendations as the Secretary deems appropriate.''.

(2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting ''and section 1905(p)(5)(A)(ii)'' after ''Subject to subsection (g)''.

(e) APPLICATION OF COST-SHARING.—Section 1902(n)(2) (42 U.S.C. 1396a(n)(2)) is amended by adding at the end the following: ''The previous sentence shall not apply to medicare cost-sharing relating to benefits under part D of title XVIII.''.

(f) EFFECTIVE DATE.—The amendments made by this section apply to medical assistance for premiums and cost-sharing incurred on or after January 1, 2005, with regard to whether regulations to implement such amendments are promulgated by such date.

SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXPANSION OF MEMBERSHIP.—

(1) IN GENERAL.—Section 1805(c) (42 U.S.C. 1395b–6(c)) is amended—

(A) in paragraph (1), by striking ''17'' and inserting ''19''; and

(B) in paragraph (2)(B), by inserting ''experts in the area of pharmacology and prescription medicine benefit programs,'' after ''other health professionals,''.

(2) INITIAL TERMS OF ADDITIONAL MEMBERS.—

(A) IN GENERAL.—For purposes of staggering the initial terms of members of the Medicare Payment Advisory Commission under section 1805(c)(3) of the Social Security Act (42 U.S.C. 1395b–6(c)(3)), the initial

terms of the 2 additional members of the Commission provided for by the amendment under paragraph (1)(A) are as follows:

(i) One member shall be appointed for 1 year.

(ii) One member shall be appointed for 2 years.

(B) COMMENCEMENT OF TERMS.—Such terms shall begin on January 1, 2003.

(b) EXPANSION OF DUTIES.—Section 1805(b)(2) (42 U.S.C. 1395b–6(b)(2)) is amended by adding at the end the following new subparagraph:

''(D) PRESCRIPTION MEDICINE BENEFIT PROGRAM.—Specifically, the Commission shall review, with respect to the prescription medicine benefit program under part D, the following:

''(i) The methodologies used for the management of costs and utilization of prescription medicines.

''(ii) The prices negotiated and paid, including trends in such prices and applicable discounts and comparisons with prices under section 1859E(a)(2)(E).

''(iii) The relationship of pharmacy acquisition costs to the prices so negotiated and paid.

''(iv) The methodologies used to ensure access to covered outpatient prescription medicines and to ensure quality in the appropriate dispensing and utilization of such medicines.

''(v) The impact of the program on promoting the development of breakthrough medicines.''.

Subtitle B—Affordable Pharmaceuticals

PART I—GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS

SEC. 111. ACCELERATED GENERIC DRUG COMPETITION.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)(iv), by striking subclause (II) and inserting the following:

''(II) the earlier of—

''(aa) the date of a final decision of a court in an action described in clause (iii)(II) (from which no appeal can or has been taken, other than a petition to the Supreme Court for a writ of certiorari) holding the patent that is the subject of the certification to be invalid or not infringed; or

''(bb) the date of a settlement order or consent decree in such an action signed by a Federal judge that enters a final judgment and includes a finding that the patent that is the subject of the certification is invalid or not infringed;'';

(2) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

(3) by inserting before subparagraph (E) (as so redesignated) the following subparagraph:

''(D)(i) The 180-day period described in subparagraph (B)(iv) shall be forfeited by the previous applicant if—

''(I) the previous applicant fails to market the drug by the later of the date 60 days after the date on which the approval of the application for the drug is made effective under subparagraph (B)(iii) or, if such approval has been made effective, and if an action has been brought against the previous applicant for infringement of a patent subject to a certification under paragraph (2)(A)(vii)(IV), or an action has been brought by the previous applicant for a declaratory judgment that such a patent is invalid or not in-

fringed, the date 60 days after the date of a final decision in such action, if there is no other such action pending by or against the previous applicant; except, however, that either of such dates may be extended due to extraordinary or unusual circumstances, as determined by the Secretary;

"(II) the previous applicant withdraws the application;

"(III) the previous applicant amends the certification from a certification under subclause (IV) of paragraph (2)(A)(vii) to a certification under subclause (III) of such paragraph, either voluntarily or as a result of a settlement or defeat in patent litigation;

"(IV) the previous applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by—

"(aa) a change in the requirements for tentative approval of the application imposed after the date on which the application was filed; or

"(bb) other extraordinary or unusual circumstances, as determined by the Secretary;

"(V) in a case in which, after the date on which the previous application was submitted under this subsection, new patent information is submitted under subsection (c)(2) for the listed drug for a patent for which certification or a method of use statement is required under paragraph (2)(A), the previous applicant fails to submit no later than 60 days from the date the applicant receives notice from the Secretary under paragraph (7)(A)(iii) of the submission of the new patent information either a certification described in paragraph (2)(A)(vii)(IV) or a statement that the method of use patent does not claim a use for which the applicant is seeking approval under this subsection in accordance with paragraph (2)(A)(viii); except, however, that such date may be extended due to extraordinary or unusual circumstances, as determined by the Secretary; or

"(VI) the previous applicant is determined by the Secretary, after a fair and sufficient hearing and in consultation with the Federal Trade Commission, to have engaged in anticompetitive or collusive conduct, or any other conduct intended to unfairly monopolize the commercial manufacturing of the drug of the application.

"(ii) If under clause (i) the previous applicant referred to in subparagraph (B)(iv) forfeits the 180-day period described in such subparagraph, such period shall become available to the next applicant submitting an application containing a certification under paragraph (2)(A)(vii)(IV) if—

"(I) no action described in subparagraph (B)(iii)(II) was brought against or by the previous applicant, or such an action was brought but did not result in a final judgment that included a finding that the patent involved is invalid; and

"(II) an action described in subparagraph (B)(iii)(II) is brought against or by the next applicant, and such action results in a final judgment that includes a finding that the patent involved is invalid.

"(iii) The 180-day period described in subparagraph (B)(iv) shall be available only to—

"(I) the previous applicant submitting an application for a drug under this subsection containing a certification described in paragraph (2)(A)(vii)(IV) with respect to any patent; or

"(II) under clause (ii), the next applicant submitting an application for a drug under this subsection containing such a certification with respect to any patent;

even if an application has been submitted for the drug under this subsection containing such a certification with respect to a different patent.

"(iv) The 180-day period described in subparagraph (B)(iv) for an application containing a certification described in paragraph (2)(A)(vii)(IV) shall apply only if an action is brought for infringement of a patent that is the subject of the certification or the applicant brings an action (not later than

60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received) against the holder of the approved application for the listed drug.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before June 7, 2002.

SEC. 112. PATENT CERTIFICATION.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B), by striking clause (iii) and inserting the following:

''(iii)(I) If the applicant made a certification described in paragraph (2)(A)(vii)(IV) and—

''(aa) no action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; and

''(bb) the applicant does not bring an action for declaratory judgment authorized in subclause (II) before the expiration of the 60-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received;

the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received, provided none of the conditions for denial of approval in paragraph (4) apply.

''(II) With respect to an applicant who made a certification described in paragraph (2)(A)(vii)(IV), if an action referred to in item (aa) of subclause (I) is brought before the expiration of the period described in such item, or if the applicant brings an action for declaratory judgment of invalidity or noninfringement of such patent (which action

is hereby authorized) before the expiration of the period described in item (bb) of such subclause, the approval shall, provided none of the conditions for denial of approval in paragraph (4) apply, be made effective in accordance with the following:

"(aa) If the action is an action referred to in subclause (I)(aa), and neither the holder of the approved application nor the owner of the patent seek a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale (or both) of the drug, the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received.

"(bb) If the action is an action referred to in subclause (I)(aa), and such a preliminary injunction is sought and the court denies the motion, the approval shall be made effective on the date on which the court denies the injunction.

"(cc) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent is invalid or was not infringed, the approval shall be made effective on the date of the decision of the court.

"(dd) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent was infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code."; and

(2) by inserting before subparagraph (D) (as added by section 111(a)(3)) the following subparagraph:

"(C) With respect to a civil action described in subparagraph (B)(iii)(II):

"(i) Each of the parties shall reasonably cooperate in expediting the action.

"(ii) If the notice under paragraph (2)(B)(ii) contains an address for the receipt of expedited notification of such

an action, the plaintiff shall, on the date the complaint is filed in the court, simultaneously cause a notification of such action to be delivered to such address by the next business day.

''(iii) An action for a declaratory judgment authorized in such subparagraph may not be brought by the applicant until the expiration of 45 days after the date the notice provided under paragraph (2)(B)(ii) was received, except that if information on the patent involved has been published under subsection (c)(2) for at least one year after the date on which the application under this subsection was filed in relation to the listed drug involved, the applicant may immediately bring such an action for declaratory judgment.

''(iv) Any such action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business.''.

(b) NEW DRUG APPLICATIONS.—Section 505(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)) is amended by striking subparagraph (C) and inserting the following:

''(C)(i)(I) If the applicant made a certification described in subsection (b)(2)(A)(iv) and—

''(aa) no action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under subsection (b)(3)(B) was received; and

''(bb) the applicant does not bring an action for declaratory judgment authorized in subclause (II) before the expiration of the 60-day period beginning on the date on which the notice provided under subsection (b)(3)(B) was received;

the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under subsection (b)(3)(B) was received, provided that none of the conditions for refusal of approval in subsection (d) apply.

"(II) With respect to an applicant who made a certification described in subsection (b)(2)(A)(iv), if an action referred to in item (aa) of subclause (I) is brought before the expiration of the period described in such item, or if the applicant brings an action for declaratory judgment of invalidity or noninfringement of such patent (which action is hereby authorized) before the expiration of the period described in item (bb) of such subclause, the approval shall, provided none of the conditions for refusal of approval in subsection (d) apply, be made effective in accordance with the following:

"(aa) If the action is an action referred to in subclause (I)(aa), and neither the holder of the approved application nor the owner of the patent seek a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale (or both) of the drug, the approval shall be made effective on the expiration of 60 days after the date on which the notice provided under subsection (b)(3)(B) was received.

"(bb) If the action is an action referred to in subclause (I)(aa), and such a preliminary injunction is sought and the court denies the motion, the approval shall be made effective on the date on which the court denies the injunction.

"(cc) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent is invalid or was not infringed, the approval shall be made effective on the date of the decision of the court.

"(dd) If neither item (aa) nor (bb) applies, and the holding of the court in the decision in the action is that the patent was infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code.

"(ii) With respect to a civil action described in clause (i)(II):

''(I) Each of the parties shall reasonably cooperate in expediting the action.

''(II) If the notice under subsection (b)(3)(B) contains an address for the receipt of expedited notification of such an action, the plaintiff shall, on the date the complaint is filed in the court, simultaneously cause a notification of such action to be delivered to such address by the next business day.

''(III) An action for a declaratory judgment authorized in such clause may not be brought by the applicant until the expiration of 45 days after the date the notice provided under subsection (b)(3)(B) was received, except that if information on the patent involved has been published under paragraph (2) for at least one year after the date on which the application was filed in relation to the drug involved, the applicant may immediately bring such an action for declaratory judgment.

''(IV) Any such action shall be brought in the judicial district in which the defendant has its principal place of business or a regular and established place of business.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall not apply to an application submitted under section 505(b)(1) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) before June 7, 2002.

SEC. 113. ADDITIONAL USES.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following paragraph:''

''(10)(A) A drug for which an application has been submitted or approved under this subsection shall not be considered ineligible for approval under this subsection or misbranded under section 502 on the basis that the labeling of the drug omits a use or any other aspect of labeling when the omitted use or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of paragraph (5)(D).

''(B) Notwithstanding clauses (iii) and (iv) of paragraph (5)(D), the Secretary may require that the labeling of a drug approved under this subsection that omits a use or other aspect of labeling as described in subparagraph (A) include—

''(i) any statement that the Secretary considers necessary for the safe use of the drug, such as appropriate contraindications, warnings, or precautions; and

''(ii) a statement that, because of marketing exclusivity for a manufacturer, the drug is not labeled for the use.''.

PART II—NOTIFICATION OF AGREEMENTS AFFECTING THE SALE OR MARKETING OF GENERIC DRUGS

SEC. 121. DEFINITIONS.

In this part:

(1) AGREEMENT.—The term ''agreement'' means an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

(2) ANTITRUST LAWS.—The term ''antitrust laws'' has the same meaning as in section 1 of the Clayton Act (15 U.S.C. 12), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(3) ANDA.—The term ''ANDA'' means an Abbreviated New Drug Application, as defined under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(4) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means a person engaged in the manufacture or marketing of a drug approved under section 505(b) of the Federal Food, Drug and Cosmetic Act.

(5) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(6) FDA.—The term ''FDA'' means the United States Food and Drug Administration.

(7) GENERIC DRUG.—The term ''generic drug'' means a product that is the subject of an ANDA.

(8) GENERIC DRUG APPLICANT.—The term ''generic drug applicant'' means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug and Cosmetic Act.

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 122. NOTIFICATION OF AGREEMENTS AFFECTING THE SALE OR MARKETING OF GENERIC DRUGS.

A brand name drug company and a generic drug applicant that enter into an agreement regarding the sale or manufacture of a generic drug that the Secretary has determined is the therapeutic equivalent of a brand name drug that is manufactured or marketed by that brand name drug company, or for which the generic drug applicant seeks such a determination of therapeutic equivalence, and which agreement could have the effect of limiting the research, development, manufacture, marketing, or selling of a generic drug that has been or could be approved for sale by the FDA pursuant to an ANDA, shall file with the Commission and the Secretary the text of the agreement, an explanation of the purpose and scope of the agreement, and an explanation of whether the agreement could delay, restrain, limit, or in any way interfere with the production, manufacture, or sale of the generic version of the drug in question.

SEC. 123. FILING DEADLINES.

Any notice, agreement, or other material required to be filed under section 122 shall be filed with the Commission and the Secretary not later than 10 business days after the date the agreement is executed.

SEC. 124. ENFORCEMENT.

(a) CIVIL FINE.—Any person, or any officer, director, or partner thereof, who fails to comply with any provision of this part shall be liable for a civil penalty of not more than $20,000 for each day during which such person is in violation of this

part. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any person, or any officer, director, partner, agent, or employee thereof, fails to comply with the notification requirement under section 122 of this part, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Commission or the Assistant Attorney General.

SEC. 125. RULEMAKING.

The Commission, in consultation with the Secretary, and with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this part—

(1) may require that the notice described in section 122 of this part be in such form and contain such documentary material and information relevant to the agreement as is necessary and appropriate to enable the Commission and the Assistant Attorney General to determine whether such agreement may violate the antitrust laws;

(2) may define the terms used in this part;

(3) may exempt classes of persons or agreements from the requirements of this part; and

(4) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this part.

SEC. 126. EFFECTIVE DATES.

This part shall take effect 90 days after the date of enactment of this Act.

TITLE II—MEDICARE+CHOICE REVITALIZATION AND MEDICARE+CHOICE COMPETITION PROGRAM

SEC. 201. MEDICARE+CHOICE IMPROVEMENTS.

(a) EQUALIZING PAYMENTS BETWEEN FEE-FOR-SERVICE AND MEDICARE+CHOICE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended by adding at the end the following:

''(D) BASED ON 100 PERCENT OF FEE-FOR-SERVICE COSTS.—

''(i) IN GENERAL.—For 2003 and 2004, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for the Medicare+Choice payment area for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in a Medicare+Choice plan under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

''(ii) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.''.

(2) CONFORMING AMENDMENT.—Such section is further amended, in the matter before subparagraph (A), by striking ''or (C)'' and inserting ''(C), or (D)''.

(b) REVISION OF BLEND.—

(1) REVISION OF NATIONAL AVERAGE USED IN CALCULATION OF BLEND.—Section 1853(c)(4)(B)(i)(II) (42 U.S.C. 1395w–23(c)(4)(B)(i)(II)) is amended by inserting ''who (with respect to determinations for 2003 and for 2004) are enrolled in a Medicare+Choice plan'' after ''the average number of medicare beneficiaries''.

(2) CHANGE IN BUDGET NEUTRALITY.—Section 1853(c) (42 U.S.C. 1395w–23(c)) is amended—

(A) in paragraph (1)(A), by inserting ''(for a year before 2003)'' after ''multiplied''; and

(B) in paragraph (5), by inserting ''(before 2003)'' after ''for each year''.

(c) REVISION IN MINIMUM PERCENTAGE INCREASE FOR 2003 AND 2004.—Section 1853(c)(1)(C) (42 U.S.C. 1395w–23(c)(1)(C)) is amended by striking clause (iv) and inserting the following:

''(iv) For 2002, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for 2001.

''(v) For 2003 and 2004, 103 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.

''(iv) For 2005 and each succeeding year, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.''.

(d) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN CALCULATION OF MEDICARE+CHOICE PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w–23(c)(3)) is amended—

(1) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (E)'', and

(2) by adding at the end the following new subparagraph:

"(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 2003), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be adjusted to include in the rate the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.".

(e) ANNOUNCEMENT OF REVISED MEDICARE+CHOICE PAYMENT RATES.—Within 2 weeks after the date of the enactment of this Act, the Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties) Medicare+Choice capitation rates under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for 2003, revised in accordance with the provisions of this section.

(f) MEDPAC STUDY OF AAPCC.—

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC) under section 1876(a)(4) of the Social Security Act (42 U.S.C. 1395mm(a)(4)). Such study shall examine—

(A) the bases for variation in such costs between different areas, including differences in input prices, utilization, and practice patterns;

(B) the appropriate geographic area for payment under the Medicare+Choice program under part C of title XVIII of such Act; and

(C) the accuracy of risk adjustment methods in reflecting differences in costs of providing care to dif-

ferent groups of beneficiaries served under such program.

(2) REPORT.—Not later than 9 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1). Such report shall include recommendations regarding changes in the methods for computing the adjusted average per capita cost among different areas.

(g) APPLYING LIMITATIONS ON BALANCE BILLING TO MEDICARE MSAS.—Section 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is amended by inserting ''or with an organization offering a MSA plan'' after ''section 1851(a)(2)(A)''.

(h) REPORT ON IMPACT OF INCREASED FINANCIAL ASSISTANCE TO MEDICARE+CHOICE PLANS.—Not later than July 1, 2003, the Secretary shall submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts (including the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and BIPA) on the availability of Medicare+Choice plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

SEC. 202. MAKING PERMANENT CHANGE IN MEDICARE+CHOICE REPORTING DEADLINES AND ANNUAL, COORDINATED ELECTION PERIOD.

(a) CHANGE IN REPORTING DEADLINE.—Section 1854(a)(1) (42 U.S.C. 1395w–24(a)(1)), as amended by section 532(b)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking ''2002, 2003, and 2004 (or July 1 of each other year)'' and inserting ''2002 and each subsequent year (or July 1 of each year before 2002)''.

(b) DELAY IN ANNUAL, COORDINATED ELECTION PERIOD.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–21(e)(3)(B)), as amended by section 532(c)(1)(A) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking ''and after 2005, the month of Novem-

ber before such year and with respect to 2003, 2004, and 2005'' and inserting '', the month of November before such year and with respect to 2003 and any subsequent year''.

(c) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—Section 1853(b)(1) (42 U.S.C. 1395w–23(b)(1)), as amended by section 532(d)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking ''and after 2005 not later than March 1 before the calendar year concerned and for 2004 and 2005'' and inserting ''not later than March 1 before the calendar year concerned and for 2004 and each subsequent year''.

(d) REQUIRING PROVISION OF AVAILABLE INFORMATION COMPARING PLAN OPTIONS.—The first sentence of section 1851(d)(2)(A)(ii) (42 U.S.C. 1395w–21(d)(2)(A)(ii)) is amended by inserting before the period the following: ''to the extent such information is available at the time of preparation of materials for the mailing''.

SEC. 203. SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)) is amended by adding at the end the following new sentence: ''Specialized Medicare+Choice plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan.''.

(b) SPECIALIZED MEDICARE+CHOICE PLAN FOR SPECIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding at the end the following new paragraph:

''(4) SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—

''(A) IN GENERAL.—The term 'specialized Medicare+Choice plan for special needs beneficiaries' means a Medicare+Choice plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

''(B) SPECIAL NEEDS BENEFICIARY.—The term 'special needs beneficiary' means a Medicare+Choice eligible individual who—

''(i) is institutionalized (as defined by the Secretary);

''(ii) is entitled to medical assistance under a State plan under title XIX; or

''(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized Medicare+Choice plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.''.

(c) RESTRICTION ON ENROLLMENT PERMITTED.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

''(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare+Choice plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2007, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs beneficiaries.''.

(d) REPORT TO CONGRESS.—Not later than December 31, 2005, the Secretary shall submit to Congress a report that assesses the impact of specialized Medicare+Choice plans for special needs beneficiaries on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall take effect upon the date of the enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS BENEFICIARIES; TRANSITION.—No later

than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue final regulations to establish requirements for special needs beneficiaries under section 1859(b)(4)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC. 204. EXTENSION OF REASONABLE COST AND SHMO CONTRACTS.

(a) REASONABLE COST CONTRACTS.—

(1) IN GENERAL.—Section 1876(h)(5)(C) (42 U.S.C. 1395mm(h)(5)(C)) is amended—

(A) by inserting ''(i)'' after ''(C)'';

(B) by inserting before the period the following: '', except (subject to clause (ii)) in the case of a contract for an area which is not covered in the service area of 1 or more coordinated care Medicare+Choice plans under part C''; and

(C) by adding at the end the following new clause:

''(ii) In the case in which—

''(I) a reasonable cost reimbursement contract includes an area in its service area as of a date that is after December 31, 2003;

''(II) such area is no longer included in such service area after such date by reason of the operation of clause (i) because of the inclusion of such area within the service area of a Medicare+Choice plan; and

''(III) all Medicare+Choice plans subsequently terminate coverage in such area;

such reasonable cost reimbursement contract may be extended and renewed to cover such area (so long as it is not included in the service area of any Medicare+Choice plan).''.

(2) STUDY.—The Secretary shall conduct a study of an appropriate transition for plans offered under reasonable cost contracts under section 1876 of the Social Security Act on and after January 1, 2005. Such a transition may take into account whether there are one or more coordinated care Medicare+Choice plans being offered in the areas involved. Not later than February 1, 2004, the Sec-

retary shall submit to Congress a report on such study and shall include recommendations regarding any changes in the amendment made by paragraph (1) as the Secretary determines to be appropriate.

(b) EXTENSION OF SOCIAL HEALTH MAINTENANCE ORGANIZATION (SHMO) DEMONSTRATION PROJECT.—

(1) IN GENERAL.—Section 4018(b)(1) of the Omnibus Budget Reconciliation Act of 1987 is amended by striking ''the date that is 30 months after the date that the Secretary submits to Congress the report described in section 4014(c) of the Balanced Budget Act of 1997'' and inserting ''December 31, 2004''.

(2) SHMOS OFFERING MEDICARE+CHOICE PLANS.—Nothing in such section 4018 shall be construed as preventing a social health maintenance organization from offering a Medicare+Choice plan under part C of title XVIII of the Social Security Act.

SEC. 205. CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT.

(a) IN GENERAL.—Section 1851(e)(2) (42 U.S.C. 1395w–21(e)(2)) is amended to read as follows:

''(2) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT.—Subject to paragraph (5), a Medicare+Choice eligible individual may change the election under subsection (a)(1) at any time.''.

(b) CONFORMING AMENDMENTS.—

(1) MEDICARE+CHOICE.—Section 1851(e) (42 U.S.C. 1395w–21(e)) is amended—

(A) in paragraph (4)—

(i) by striking ''Effective as of January 1, 2002, an'' and inserting ''An'';

(ii) by striking ''other than during an annual, coordinated election period'';

(iii) by inserting ''in a special election period for such purpose'' after ''make a new election under this section''; and

(iv) by striking the second sentence; and

(B) in paragraphs (5)(B) and (6)(A), by striking ''the first sentence of''.

(2) PERMITTING ENROLLMENT IN MEDIGAP WHEN M+C PLANS REDUCE BENEFITS OR WHEN PROVIDER LEAVES A M+C PLAN.—

(A) IN GENERAL.—Clause (ii) of section 1882(s)(3)(B) (42 U.S.C. 1395ss(s)(3)(B)) is amended—

(i) by inserting ''(I)'' after ''(ii)'';

(ii) by striking ''under the first sentence of'' each place it appears and inserting ''during a special election period provided for under'';

(iii) by inserting ''the circumstances described in subclause (II) are present or'' before ''there are circumstances''; and

(iv) by adding at the end the following new subclause:

''(II) The circumstances described in this subclause are, with respect to an individual enrolled in a Medicare+Choice plan, a reduction in benefits (including an increase in cost-sharing) offered under the Medicare+Choice plan from the previous year or a provider of services or physician who serves the individual no longer participating in the plan (other than because of good cause relating to quality of care under the plan).''.

(B) CONFORMING AMENDMENT.—Clause (iii) of such section is amended—

(i) by inserting ''the circumstances described in clause (ii)(II) are met or'' after ''policy described in subsection (t), and''; and

(ii) by striking ''under the first sentence of'' and inserting ''during a special election period provided for under''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2003, and shall apply to reductions in benefits and changes in provider participation occurring on or after such date.

SEC. 206. LIMITATION ON MEDICARE+CHOICE COST-SHARING.

(a) IN GENERAL.—Section 1852(a) (42 U.S.C. 1395w–22(a)) is amended by adding at the end the following new paragraph:

''(6) LIMITATION ON COST-SHARING.—

''(A) IN GENERAL.—Subject to subparagraph (B), in no case shall the cost-sharing with respect to an item or service under a Medicare+Choice plan exceed the cost-sharing otherwise applicable under parts A and B to an individual who is not enrolled in a Medicare+Choice plan under this part.

''(B) PERMITTING FLAT COPAYMENTS.—Subparagraph (A) shall not be construed as preventing the application of flat dollar copayment amounts (in place of a percentage coinsurance), such as a fixed copayment for a doctor's visit, so long as such amounts are reasonable and appropriate and do not adversely affect access to items and services (as determined by the Secretary).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply as of January 1, 2003.

SEC. 207. EXTENSION OF MUNICIPAL HEALTH SERVICE DEMONSTRATION PROJECTS.

The last sentence of section 9215(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as previously amended, is amended by striking ''December 31, 2004, but only with respect to'' and all that follows and inserting ''December 31, 2009, but only with respect to individuals who reside in the city in which the project is operated and so long as the total number of individuals participating in the project does not exceed the number of such individuals participating as of January 1, 1996.''.

TITLE III—RURAL HEALTH CARE IMPROVEMENTS

SEC. 301. REFERENCE TO FULL MARKET BASKET INCREASE FOR SOLE COMMUNITY HOSPITALS.

For provision eliminating any reduction from full market basket in the update for inpatient hospital services for sole community hospitals, see section 401.

SEC. 302. ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) TREATMENT FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

(a) BLENDING OF PAYMENT AMOUNTS.—

(1) IN GENERAL.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended by adding at the end the following new clause:

''(xiv)(I) In the case of discharges in a fiscal year beginning on or after October 1, 2002, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the old blend proportion (specified under subclause (III)) of the disproportionate share adjustment percentage otherwise determined under the respective clause and 100 percent minus such old blend proportion of the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

''(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 10 percent for a hospital that is not classified as a rural referral center under subparagraph (C).

''(III) For purposes of subclause (I), the old blend proportion for fiscal year 2003 is 66⅔ percent, for fiscal year 2004 is 33⅓ percent subsequent year, and for each fiscal year beginning with 2005 is 0 percent.''.

(2) CONFORMING AMENDMENTS.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

(A) in each of subclauses (II), (III), (IV), (V), and (VI) of clause (iv), by inserting ''subject to clause (xiv) and'' before ''for discharges occurring'';

(B) in clause (viii), by striking ''The formula'' and inserting ''Subject to clause (xiv), the formula''; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking ''For purposes'' and inserting ''Subject to clause (xiv), for purposes''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to discharges occurring on or after October 1, 2002.

SEC. 303. 2-YEAR PHASED-IN INCREASE IN THE STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS TO ACHIEVE A SINGLE, UNIFORM STANDARDIZED AMOUNT.

Section 1886(d)(3)(A)(iv) (42 U.S.C. 1395ww(d)(3)(A)(iv)) is amended—

(1) by striking ''(iv) For discharges'' and inserting ''(iv)(I) Subject to the succeeding provisions of this clause, for discharges''; and

(2) by adding at the end the following new subclauses:

''(II) For discharges occurring during fiscal year 2003, the average standardized amount for hospitals located other than in a large urban area shall be increased by ½ of the difference between the average standardized amount determined under subclause (I) for hospitals located in large urban areas for such fiscal year and such amount determined (without regard to this subclause) for other hospitals for such fiscal year.

''(III) For discharges occurring in a fiscal year beginning with fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in any area within the United States and within each region equal to the average standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2005, for hospitals located in any area) increased by the

applicable percentage increase under subsection (b)(3)(B)(i).''.

SEC. 304. MORE FREQUENT UPDATE IN WEIGHTS USED IN HOSPITAL MARKET BASKET.

(a) MORE FREQUENT UPDATES IN WEIGHTS.—After revising the weights used in the hospital market basket under section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(iii)) to reflect the most current data available, the Secretary shall establish a frequency for revising such weights in such market basket to reflect the most current data available more frequently than once every 5 years.

(b) REPORT.—Not later than October 1, 2003, the Secretary shall submit a report to Congress on the frequency established under subsection (a), including an explanation of the reasons for, and options considered, in determining such frequency.

SEC. 305. IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL PROGRAM.

(a) REINSTATEMENT OF PERIODIC INTERIM PAYMENT (PIP).—Section 1815(e)(2) (42 U.S.C. 1395g(e)(2)) is amended—

(1) by striking ''and'' at the end of subparagraph (C);

(2) by adding ''and'' at the end of subparagraph (D); and

(3) by inserting after subparagraph (D) the following new subparagraph:

''(E) inpatient critical access hospital services;''.

(b) CONDITION FOR APPLICATION OF SPECIAL PHYSICIAN PAYMENT ADJUSTMENT.—Section 1834(g)(2) (42 U.S.C. 1395m(g)(2)) is amended by adding after and below subparagraph (B) the following:

''The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to

those physicians who have not assigned such billing rights.''.

(c) FLEXIBILITY IN BED LIMITATION FOR HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUATIONS.—Section 1820 (42 U.S.C. 1395i–4) is amended—

(1) in subsection (c)(2)(B)(iii), by inserting ''subject to paragraph (3)'' after ''(iii) provides'';

(2) by adding at the end of subsection (c) the following new paragraph:

''(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR HOSPITALS WITH STRONG SEASONAL CENSUS FLUCTUATIONS.—

''(A) IN GENERAL.—In the case of a hospital that demonstrates that it meets the standards established under subparagraph (B), the bed limitations otherwise applicable under paragraph (2)(B)(iii) and subsection (f) shall be increased by 5 beds.

''(B) STANDARDS.—The Secretary shall specify standards for determining whether a critical access hospital has sufficiently strong seasonal variations in patient admissions to justify the increase in bed limitation provided under subparagraph (A).''; and

(3) in subsection (f), by adding at the end the following new sentence: ''The limitations in numbers of beds under the first sentence are subject to adjustment under subsection (c)(3).''.

(d) 5-YEAR EXTENSION OF THE AUTHORIZATION FOR APPROPRIATIONS FOR GRANT PROGRAM.—Section 1820(j) (42 U.S.C. 1395i–4(j)) is amended by striking ''through 2002'' and inserting ''through 2007''.

(e) PROHIBITION OF RETROACTIVE RECOUPMENT.—The Secretary shall not recoup (or otherwise seek to recover) overpayments made for outpatient critical access hospital services under part B of title XVIII of the Social Security Act, for services furnished in cost reporting periods that began before October 1, 2002, insofar as such overpayments are attributable to payment being based on 80 percent of reasonable costs (instead

of 100 percent of reasonable costs minus 20 percent of charges).

(f) EFFECTIVE DATES.—

(1) REINSTATEMENT OF PIP.—The amendments made by subsection (a) shall apply to payments made on or after January 1, 2003.

(2) PHYSICIAN PAYMENT ADJUSTMENT CONDITION.—The amendment made by subsection (b) shall be effective as if included in the enactment of section 403(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (113 Stat. 1501A–371).

(3) FLEXIBILITY IN BED LIMITATION.—The amendments made by subsection (c) shall apply to designations made on or after January 1, 2003, but shall not apply to critical access hospitals that were designated as of such date.

SEC. 306. EXTENSION OF TEMPORARY INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) IN GENERAL.—Section 508(a) of BIPA (114 Stat. 2763A–533) is amended—

(1) by striking ''24-MONTH INCREASE BEGINNING APRIL 1, 2001'' and inserting ''IN GENERAL''; and

(2) by striking ''April 1, 2003'' and inserting ''January 1, 2005''.

(b) CONFORMING AMENDMENT.—Section 547(c)(2) of BIPA (114 Stat. 2763A–553) is amended by striking ''the period beginning on April 1, 2001, and ending on September 30, 2002,'' and inserting ''a period under such section''.

SEC. 307. REFERENCE TO 10 PERCENT INCREASE IN PAYMENT FOR HOSPICE CARE FURNISHED IN A FRONTIER AREA AND RURAL HOSPICE DEMONSTRATION PROJECT.

For—

(1) provision of 10 percent increase in payment for hospice care furnished in a frontier area, see section 422; and

(2) provision of a rural hospice demonstration project, see section 423.

SEC. 308. REFERENCE TO PRIORITY FOR HOSPITALS LOCATED IN RURAL OR SMALL URBAN AREAS IN REDISTRIBUTION OF UNUSED GRADUATE MEDICAL EDUCATION RESIDENCIES.

For provision providing priority for hospitals located in rural or small urban areas in redistribution of unused graduate medical education residencies, see section 611.

SEC. 309. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians' services in different geographic areas. Such study shall include—

(1) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

(2) an evaluation of the measures used for such adjustment, including the frequency of revisions; and

(3) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice component.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include recommendations regarding the use of more current data in computing geographic cost of practice indices as well as the use of data directly representative of physicians' costs (rather than proxy measures of such costs).

SEC. 310. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a–7(b)(3)), as amended by section 101(b)(2), is amended—

(1) in subparagraph (F), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(H) any remuneration between a public or nonprofit private health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations or loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.''.

(b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ''Secretary'') shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER.—The Secretary shall consider the following factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and the other party restricts or limits a patient's freedom of choice.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) INTERIM FINAL EFFECT.—No later than 180 days after the date of enactment of this Act, the Secretary shall publish a rule in the Federal Register consistent with the factors under paragraph (1)(B). Such rule shall be effective and final immediately on an interim basis, subject to such change and revision, after public notice and opportunity (for a period of not more than 60 days) for public comment, as is consistent with this subsection.

SEC. 311. RELIEF FOR CERTAIN NON-TEACHING HOSPITALS.

(a) IN GENERAL.—In the case of a non-teaching hospital that meets the condition of subsection (b), for its cost reporting period beginning in each of fiscal years 2003, 2004, and 2005 the amount of payment made to the hospital under section 1886(d) of the Social Security Act for discharges occurring during such fiscal year only shall be increased as though the applicable percentage increase (otherwise applicable to discharges occurring during such fiscal year under section 1886(b)(3)(B)(i) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(i)) had been increased by 5 percentage points. The previous sentence shall be applied for each such fiscal year separately without regard to its application in a pre-

vious fiscal year and shall not affect payment for discharges for any hospital occurring during a fiscal year after fiscal year 2005.

(b) CONDITION.—A non-teaching hospital meets the condition of this paragraph if—

(1) it is located in a rural area and the amount of the aggregate payments under subsection (d) of such section for non-teaching hospitals located in rural areas in the State for their cost reporting periods beginning during fiscal year 1999 is less than the aggregate allowable operating costs of inpatient hospital services (as defined in section 1886(a)(4) of such Act) for all such hospitals in such areas in such State with respect to such cost reporting periods; or

(2) it is located in an urban area and the amount of the aggregate payments under subsection (d) of such section for non-teaching hospitals located in urban areas in the State for their cost reporting periods beginning during fiscal year 1999 is less than 103 percent of the aggregate allowable operating costs of inpatient hospital services (as defined in section 1886(a)(4) of such Act) for all such hospitals in such areas in such State with respect to such cost reporting periods.

The amounts under paragraphs (1) and (2) shall be determined by the Secretary of Health and Human Services based on data of the Medicare Payment Advisory Commission.

(c) DEFINITIONS.—For purposes of this section:

(1) NON-TEACHING HOSPITAL.—The term ''non-teaching hospital'' means, for a cost reporting period, a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B))) that is not receiving any additional payment under section 1886(d)(5)(B) of such Act (42 U.S.C. 1395ww(d)(5)(B)) or a payment under section 1886(h) of such Act (42 U.S.C. 1395ww(h)) for discharges occurring during the period.

(2) RURAL; URBAN.—The terms ''rural'' and ''urban'' have the meanings given such terms for purposes of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)).

TITLE IV—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 401. REVISION OF ACUTE CARE HOSPITAL PAYMENT UPDATES.

Subclause (XVIII) of section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i)) is amended to read as follows:

''(XVIII) for fiscal year 2003, the market basket percentage increase for sole community hospitals and such increase minus 0.25 percentage points for other hospitals, and''.

SEC. 402. FREEZE IN LEVEL OF ADJUSTMENT FOR INDIRECT COSTS OF MEDICAL EDUCATION (IME) THROUGH FISCAL YEAR 2007.

Section 1886(d)(5)(B)(ii) (42 U.S.C. 1395ww(d)(5)(B)(ii)) is amended—

(1) in subclause (VI), by inserting ''and each succeeding fiscal year through fiscal year 2007'' after ''2002''; and

(2) in subclause (VII), by striking ''2002'' and inserting ''2007''.

SEC. 403. RECOGNITION OF NEW MEDICAL TECHNOLOGIES UNDER INPATIENT HOSPITAL PPS.

(a) IMPROVING TIMELINESS OF DATA COLLECTION.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

''(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.''.

(b) ELIGIBILITY STANDARD.—

(1) MINIMUM PERIOD FOR RECOGNITION OF NEW TECHNOLOGIES.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

(A) by inserting ''(I)'' after ''(vi)''; and

(B) by adding at the end the following new subclause:

''(II) Under such criteria, a service or technology shall not be denied treatment as a new service or technology on the basis of the period of time in which the service or technology has been in use if such period ends before the end of the 2-to-3-year period that begins on the effective date of implementation of a code under ICD–9–CM (or a successor coding methodology) that enables the identification of a significant sample of specific discharges in which the service or technology has been used.''.

(2) ADJUSTMENT OF THRESHOLD.—Section 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is amended by inserting ''(applying a threshold specified by the Secretary that is the lesser of 50 percent of the national average standardized amount for operating costs of inpatient hospital services for all hospitals and all diagnosis-related groups or one standard deviation for the diagnosis-related group involved)'' after ''is inadequate''.

(3) CRITERION FOR SUBSTANTIAL IMPROVEMENT.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is further amended by adding at the end the following subclause:

''(III) The Secretary shall by regulation provide for further clarification of the criteria applied to determine whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries. Under such criteria, in determining whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries, the Secretary shall deem a service

or technology as meeting such requirement if the service or technology is a drug or biological that is designated under section 506 or 526 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of title 21, Code of Federal Regulations, or designated for priority review when the marketing application for such drug or biological was filed or is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority review has been provided under section 515(d)(5) of such Act.''.

(4) PROCESS FOR PUBLIC INPUT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended by paragraph (1), is amended—

(A) in clause (i), by adding at the end the following: ''Such mechanism shall be modified to meet the requirements of clause (viii).''; and

(B) by adding at the end the following new clause:

''(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology not described in the second sentence of clause (vi)(III) represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries as follows:

''(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

''(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

''(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, medicare beneficiaries, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed

rulemaking regarding whether service or technology represents a substantial improvement.''.

(c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is further amended by adding at the end the following new clause:

''(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. In such case, no add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).''.

(d) IMPROVEMENT IN PAYMENT FOR NEW TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after ''the estimated average cost of such service or technology'' the following: ''(based on the marginal rate applied to costs under subparagraph (A))''.

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—The Secretary shall implement the amendments made by this section so that they apply to classification for fiscal years beginning with fiscal year 2004.

(2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL YEAR 2003 THAT ARE DENIED.—In the case of an application for a classification of a medical service or technology as a new medical service or technology under section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was filed for fiscal year 2003 and that is denied—

(A) the Secretary shall automatically reconsider the application as an application for fiscal year 2004 under the amendments made by this section; and

(B) the maximum time period otherwise permitted for such classification of the service or technology shall be extended by 12 months.

SEC. 404. PHASE-IN OF FEDERAL RATE FOR HOSPITALS IN PUERTO RICO.

Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is amended—

(1) in subparagraph (A)—

(A) in clause (i), by striking ''for discharges beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 75 percent)'' and inserting ''the applicable Puerto Rico percentage (specified in subparagraph (E))''; and

(B) in clause (ii), by striking ''for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 25 percent)'' and inserting ''the applicable Federal percentage (specified in subparagraph (E))''; and

(2) by adding at the end the following new subparagraph:

''(E) For purposes of subparagraph (A), for discharges occurring—

''(i) between October 1, 1987, and September 30, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

''(ii) on or after October 1, 1997, and before October 1, 2003, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

''(iii) during fiscal year 2004, the applicable Puerto Rico percentage is 45 percent and the applicable Federal percentage is 55 percent;

"(iv) during fiscal year 2005, the applicable Puerto Rico percentage is 40 percent and the applicable Federal percentage is 60 percent;

"(v) during fiscal year 2006, the applicable Puerto Rico percentage is 35 percent and the applicable Federal percentage is 65 percent;

"(vi) during fiscal year 2007, the applicable Puerto Rico percentage is 30 percent and the applicable Federal percentage is 70 percent; and

"(vii) on or after October 1, 2007, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.".

SEC. 405. REFERENCE TO PROVISION RELATING TO ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

For provision enhancing disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds, see section 302.

SEC. 406. REFERENCE TO PROVISION RELATING TO 2-YEAR PHASED-IN INCREASE IN THE STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS TO ACHIEVE A SINGLE, UNIFORM STANDARDIZED AMOUNT.

For provision phasing in over a 2-year period an increase in the standardized amount for rural and small urban areas to achieve a single, uniform, standardized amount, see section 303.

SEC. 407. REFERENCE TO PROVISION FOR MORE FREQUENT UPDATES IN THE WEIGHTS USED IN HOSPITAL MARKET BASKET.

For provision providing for more frequent updates in the weights used in hospital market basket, see section 304.

SEC. 408. REFERENCE TO PROVISION MAKING IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL PROGRAM.

For provision providing making improvements to critical access hospital program, see section 305.

Subtitle B—Skilled Nursing Facility Services

SEC. 411. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) 5-YEAR EXTENSION OF TEMPORARY INCREASE IN NURSING COMPONENT OF PPS FEDERAL RATE.—Section 312(a) of BIPA is amended by striking ", and before October 1, 2002" and inserting "and before October 1, 2007".

(b) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—

(1) IN GENERAL.—Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is amended to read as follows:

"(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

"(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable shall be increased by 128 percent to reflect increased costs associated with such residents.

"(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to services furnished on or after October 1, 2003.

Subtitle C—Hospice

SEC. 421. COVERAGE OF HOSPICE CONSULTATION SERVICES.

(a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

(1) by striking "and" at the end of paragraph (3);

(2) by striking the period at the end of paragraph (4) and inserting "; and"; and

(3) by inserting after paragraph (4) the following new paragraph:

''(5) for individuals who are terminally ill, have not made an election under subsection (d)(1), and have not previously received services under this paragraph, services that are furnished by a physician who is the medical director or an employee of a hospice program and that consist of—

''(A) an evaluation of the individual's need for pain and symptom management;

''(B) counseling the individual with respect to end-of-life issues and care options; and

''(C) advising the individual regarding advanced care planning.''.

(b) PAYMENT.—Section 1814(i) (42 U.S.C. l395f(i)) is amended by adding at the end the following new paragraph:

''(4) The amount paid to a hospice program with respect to the services under section 1812(a)(5) for which payment may be made under this part shall be equal to an amount equivalent to the amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity under the fee schedule established under section 1848(b), other than the portion of such amount attributable to the practice expense component.''.

(c) CONFORMING AMENDMENT.—Section 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended by inserting before the comma at the end the following: ''and services described in section 1812(a)(5)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to services provided by a hospice program on or after January 1, 2004.

SEC. 422. 10 PERCENT INCREASE IN PAYMENT FOR HOSPICE CARE FURNISHED IN A FRONTIER AREA.

(a) IN GENERAL.—Section 1814(i)(1) (42 U.S.C. 1395f(i)(1)) is amended by adding at the end the following new subparagraph:

''(D) With respect to hospice care furnished in a frontier area on or after January 1, 2003, and before January 1, 2008, the payment rates otherwise established for such care shall be increased by 10 percent. For purposes of this subparagraph, the term 'frontier area' means a county in which the population density is less than 7 persons per square mile.''.

(b) REPORT ON COSTS.—Not later than January 1, 2007, the Comptroller General of the United States shall submit to Congress a report on the costs of furnishing hospice care in frontier areas. Such report shall include recommendations regarding the appropriateness of extending, and modifying, the payment increase provided under the amendment made by subsection (a).

SEC. 423. RURAL HOSPICE DEMONSTRATION PROJECT.

(a) IN GENERAL.—The Secretary shall conduct a demonstration project for the delivery of hospice care to medicare beneficiaries in rural areas. Under the project medicare beneficiaries who are unable to receive hospice care in the home for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided by hospice programs under section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

(b) SCOPE OF PROJECT.—The Secretary shall conduct the project under this section with respect to no more than 3 hospice programs over a period of not longer than 5 years each.

(c) COMPLIANCE WITH CONDITIONS.—Under the demonstration project—

(1) the hospice program shall comply with otherwise applicable requirements, except that it shall not be required to offer services outside of the home or to meet the require-

ments of section 1861(dd)(2)(A)(iii) of the Social Security Act; and

(2) payments for hospice care shall be made at the rates otherwise applicable to such care under title XVIII of such Act.

The Secretary may require the program to comply with such additional quality assurance standards for its provision of services in its facility as the Secretary deems appropriate.

(d) REPORT.—Upon completion of the project, the Secretary shall submit a report to Congress on the project and shall include in the report recommendations regarding extension of such project to hospice programs serving rural areas.

Subtitle D—Other Provisions

SEC. 431. DEMONSTRATION PROJECT FOR USE OF RECOVERY AUDIT CONTRACTORS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a demonstration project under this section (in this section referred to as the ''project'') to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying and recouping overpayments under the medicare program for services for which payment is made under part A of title XVIII of the Social Security Act. Under the project—

(1) payment may be made to such a contractor on a contingent basis;

(2) a percentage of the amount recovered may be retained by the Secretary and shall be available to the program management account of the Centers for Medicare & Medicaid Services; and

(3) the Secretary shall examine the efficacy of such use with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise.

(b) SCOPE AND DURATION.—The project shall cover at least 2 States and at least 3 contractors and shall last for not longer than 3 years.

(c) WAIVER.—The Secretary of Health and Human Services shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (a).

(d) QUALIFICATIONS OF CONTRACTORS.—

(1) IN GENERAL.—The Secretary shall enter into a recovery audit contract under this section with an entity only if the entity has staff that has knowledge of and experience with the payment rules and regulations under the medicare program or the entity has or will contract with another entity that has such knowledgeable and experienced staff.

(2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity is a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395u), or a Medicare Administrative Contractor under section 1874A of such Act, or any other entity that carries out the type of activities with respect to providers of services under part A that would constitute a conflict of interest, as determined by the Secretary.

(3) PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY WITH PRIVATE INSURERS.—In awarding contracts to recovery audit contractors under this section, the Secretary shall give preference to those entities that the Secretary determines have demonstrated proficiency in recovery audits with private insurers or under the medicaid program under title XIX of such Act.

(e) REPORT.—The Secretary of Health and Human Services shall submit to Congress a report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on savings to the medicare program and recommendations on the cost-effectiveness of extending or expanding the project.

TITLE V—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

SEC. 501. REVISION OF UPDATES FOR PHYSICIANS' SERVICES.

(a) UPDATE FOR 2003 THROUGH 2006.—

(1) IN GENERAL.—Section 1848(d) (42 U.S.C. 1395w–4(d)) is amended by adding at the end the following new paragraphs:

''(5) UPDATE FOR 2003.—The update to the single conversion factor established in paragraph (1)(C) for 2003 is 2 percent.

''(6) SPECIAL RULES FOR UPDATE FOR 2004, 2005, AND 2006.—The following rules apply in determining the update adjustment factors under paragraph (4)(B) for 2004, 2005, and 2006:

''(A) USE OF 2002 DATA IN DETERMINING ALLOWABLE COSTS.—

''(i) The reference in clause (ii)(I) of such paragraph to April 1, 1996, is deemed to be a reference to January 1, 2002.

''(ii) The allowed expenditures for 2002 is deemed to be equal to the actual expenditures for physicians' services furnished during 2002, as estimated by the Secretary.

''(B) 1 PERCENTAGE POINT INCREASE IN GDP UNDER SGR.—The annual average percentage growth in real gross domestic product per capita under subsection (f)(2)(C) for each of 2003, 2004, 2005, and 2006 is deemed to be increased by 1 percentage point.''.

(2) CONFORMING AMENDMENT.—Paragraph (4)(B) of such section is amended, in the matter before clause (i), by inserting ''and paragraph (6)'' after ''subparagraph (D)''.

(3) NOT TREATED AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION.—

The amendments made by this subsection shall not be treated as a change in law for purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)).

(b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING GROSS DOMESTIC PRODUCT.—

(1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C. 1395w–4(f)(2)(C)) is amended—

(A) by striking ''projected'' and inserting ''annual average''; and

(B) by striking ''from the previous applicable period to the applicable period involved'' and inserting ''during the 10-year period ending with the applicable period involved''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to computations of the sustainable growth rate for years beginning with 2002.

(c) ELIMINATION OF TRANSITIONAL ADJUSTMENT.—Section 1848(d)(4)(F) (42 U.S.C. 1395w–4(d)(4)(F)) is amended by striking ''subparagraph (A)'' and all that follows and inserting ''subparagraph (A), for each of 2001 and 2002, of −0.2 percent.''

SEC. 502. STUDIES ON ACCESS TO PHYSICIANS' SERVICES.

(a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSICIANS' SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians' services under the medicare program. The study shall include—

(A) an assessment of the use by beneficiaries of such services through an analysis of claims submitted by physicians for such services under part B of the medicare program;

(B) an examination of changes in the use by beneficiaries of physicians' services over time;

(C) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include a determination whether—

(A) data from claims submitted by physicians under part B of the medicare program indicate potential access problems for medicare beneficiaries in certain geographic areas; and

(B) access by medicare beneficiaries to physicians' services may have improved, remained constant, or deteriorated over time.

(b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study on the adequacy of the supply of physicians (including specialists) in the United States and the factors that affect such supply.

(2) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

SEC. 503. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS' SERVICES.

Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall submit to Congress a report on the effect of refinements to the practice expense component of payments for physicians' services in the case of services for which there are no physician work relative value units, after the transition to a full resource-based payment system in 2002, under section 1848 of the Social Security Act (42 U.S.C. 1395w–4). Such report shall examine the following matters by physician specialty:

(1) The effect of such refinements on payment for physicians' services.

(2) The interaction of the practice expense component with other components of and adjustments to payment for physicians' services under such section.

(3) The appropriateness of the amount of compensation by reason of such refinements.

(4) The effect of such refinements on access to care by medicare beneficiaries to physicians' services.

(5) The effect of such refinements on physician participation under the medicare program.

SEC. 504. 1-YEAR EXTENSION OF TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES UNDER MEDICARE.

Section 542(c) of BIPA is amended by striking ''2-year period'' and inserting ''3-year period''.

SEC. 505. PHYSICIAN FEE SCHEDULE WAGE INDEX REVISION.

(a) IN GENERAL.—Notwithstanding any other provision of law, for purposes of payment under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians' services furnished during 2004, in no case may the work geographic index otherwise calculated under section 1848(e)(1)(A)(iii) of such Act (42 U.S.C. 1395w–4(e)(1)(A)(iii)) be less than 0.985.

(b) EXEMPTION FROM LIMITATION ON ANNUAL ADJUSTMENTS.—The increase in expenditures attributable to subsection (a) during 2004 shall not be taken into account in applying section 1848(c)(2)(B)(ii)(II) of such Act (42 U.S.C. 1395w–4(c)(2)(B)(ii)(II)) for that year.

(c) GAO REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to evaluate the following:

(A) The economic basis of the current methodology for geographic adjustment of the work component of the physician payment rate under the physician fee

schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4).

(B) Whether the adjustment under subsection (a) should be continued, and whether there is an economic basis for the continuation of such adjustment, in those areas in which the adjustment applies.

(C) The effect of the methodology on physician location and retention in areas affected by such adjustment.

(D) The differences in recruitment costs and retention rates for physicians, including specialists, between large urban areas and other areas.

(E) The mobility of physicians, including specialists, over the last decade.

(F) The effect of raising the floor of the geographic index to a value of 1.0 for adjustment of the work component.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date of the enactment of this Act.

Subtitle B—Other Services

SEC. 511. COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w–3) is amended to read as follows:

''COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

''SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

''(1) IMPLEMENTATION OF PROGRAMS.—

''(A) IN GENERAL.—The Secretary shall establish and implement programs under which, beginning in 2008, competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph

(2)) for which payment is made under this part. Such areas may differ for different items and services.

"(B) PHASED-IN IMPLEMENTATION.—The programs shall be phased-in among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs in—

"(i) at least ⅓ of such areas in 2008; and

"(ii) at least ⅔ of such areas in 2009.

"(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

"(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:

"(A) DURABLE MEDICAL EQUIPMENT AND INHALATION DRUGS USED IN CONNECTION WITH DURABLE MEDICAL EQUIPMENT.—Covered items (as defined in section 1834(a)(13)) for which payment is otherwise made under section 1834(a), other than items used in infusion, and inhalation drugs used in conjunction with durable medical equipment.

"(B) OFF-THE-SHELF ORTHOTICS.—Orthotics (described in section 1861(s)(9)) for which payment is otherwise made under section 1834(h) which require minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the patient.

"(3) EXEMPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—

"(A) areas that are not competitive due to low population density; and

"(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

"(b) PROGRAM REQUIREMENTS.—

"(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

"(2) CONDITIONS FOR AWARDING CONTRACT.—

"(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

"(i) The entity meets quality and financial standards specified by the Secretary or developed by accreditation entities or organizations recognized by the Secretary.

"(ii) The total amounts to be paid under the contract (including costs associated with the administration of the contract) are expected to be less than the total amounts that would otherwise be paid.

"(iii) Beneficiary access to a choice of multiple suppliers in the area is maintained.

"(iv) Beneficiary liability is limited to the applicable percentage of contract award price.

"(B) QUALITY STANDARDS.—The quality standards specified under subparagraph (A)(i) shall not be less than the quality standards that would otherwise apply if this section did not apply and shall include consumer services standards. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of physicians, practitioners, and suppliers to review (and advise the Secretary concerning) such quality standards.

"(3) CONTENTS OF CONTRACT.—

"(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

"(B) TERM OF CONTRACTS.—The Secretary shall rebid contracts under this section not less often than once every 3 years.

"(4) LIMIT ON NUMBER OF CONTRACTORS.—

"(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of beneficiaries for such items or services in the geographic area covered under the contract on a timely basis.

"(B) MULTIPLE WINNERS.—The Secretary shall award contracts to more than one entity submitting a bid in each area for an item or service.

"(5) PARTICIPATING CONTRACTORS.—Payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

"(A) the contractor has submitted a bid for such items and services under this section; and

"(B) the Secretary has awarded a contract to the contractor for such items and services under this section.

"(6) AUTHORITY TO CONTRACT FOR EDUCATION, OUTREACH AND COMPLAINT SERVICES.—The Secretary may enter into a contract with an appropriate entity to address complaints from beneficiaries who receive items and services from an entity with a contract under this section and

to conduct appropriate education of and outreach to such beneficiaries with respect to the program.

''(c) ANNUAL REPORTS.—The Secretary shall submit to Congress an annual management report on the programs under this section. Each such report shall include information on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction.

''(d) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

''(1) IN GENERAL.—The Secretary shall, beginning in 2008, conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

''(A) for which payment is otherwise made under section 1833(h) or 1834(d)(1) (relating to colorectal cancer screening tests); and

''(B) which are furnished without a face-to-face encounter between the individual and the hospital or physician ordering the tests.

''(2) TERMS AND CONDITIONS.—Such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2).

''(3) REPORT.—The Secretary shall submit to Congress—

''(A) an initial report on the project not later than December 31, 2009; and

''(B) such progress and final reports on the project after such date as the Secretary determines appropriate.''.

(b) CONTINUATION OF CERTAIN DEMONSTRATION PROJECTS.—Notwithstanding the amendment made by subsection (a), with respect to demonstration projects implemented by the Secretary under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) (relating to the establishment of competitive acquisition areas) that was in effect on the day before the date of the enactment of this Act, each such demonstration

project may continue under the same terms and conditions applicable under that section as in effect on that date.

(c) REPORT ON DIFFERENCES IN PAYMENT FOR LABORATORY SERVICES.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that analyzes differences in reimbursement between public and private payors for clinical diagnostic laboratory services.

(d) MEDPAC REPORT ON IMPACT OF DEMONSTRATION PROJECTS ON BENEFICIARY ACCESS TO SERVICES.—Not later than 1 year after the date of the enactment of this Act, the Medicare Pyament Advisory Commission shall submit to Congress a report that analyzes the impact of demonstration projects carried out under section 1847 of the Social Security Act, as in effect on June 1, 2002, on access by medicare beneficiaries to durable medical equipment for which payment was made under the demonstration project.

SEC. 512. PAYMENT FOR AMBULANCE SERVICES.

(a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

(1) in paragraph (2)(E), by inserting ''consistent with paragraph (10)'' after ''in an efficient and fair manner'';

(2) by redesignating the paragraph (8) added by section 221(a) of BIPA as paragraph (9); and

(3) by adding at the end the following new paragraph:

''(10) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of service furnished in a year before January 1, 2007, the portion of the payment amount that is based on the fee schedule shall not be less than the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

''(A) For 2003, the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

"(B) For 2004, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

"(C) For 2005, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

"(D) For 2006, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the 9 Census divisions using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.".

(b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—Section 1834(l), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

"(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after January 1, 2003, and before January 1, 2008, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to such miles.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to ambulance services furnished on or after January 1, 2003.

SEC. 513. 5-YEAR EXTENSION OF MORATORIUM ON THERAPY CAPS; PROVISIONS RELATING TO REPORTS.

(a) 5-YEAR EXTENSION OF MORATORIUM ON THERAPY CAPS.—Section 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking ''and 2002'' and inserting ''2002, 2003, 2004, 2005, 2006, and 2007''.

(b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES.—Not later than December 31, 2002, the Secretary shall submit to Congress the reports required under section 4541(d)(2) of the Balanced Budget Act of 1997 (relating to alternatives to a single annual dollar cap on outpatient therapy) and under section 221(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (relating to utilization patterns for outpatient therapy).

(c) IDENTIFICATION OF CONDITIONS AND DISEASES JUSTIFYING WAIVER OF THERAPY CAP.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps under section 1833(g)(4) of the Social Security Act (42 U.S.C. 1395l(g)(4)).

(2) REPORTS TO CONGRESS.—Not later than July 1, 2003, the Secretary shall submit to Congress a preliminary report on the conditions and diseases identified under paragraph (1) and not later than September 1, 2003, a final report on the conditions and diseases so identified.

(d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL THERAPIST SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access to physical therapist services in States authorizing such services without a physician referral and in States that require such a physician referral. The study shall—

(A) examine the use of and referral patterns for physical therapist services for patients age 50 and older in States that authorize such services without a physician referral and in States that require such a physician referral;

(B) examine the use of and referral patterns for physical therapist services for patients who are medicare beneficiaries;

(C) examine the potential effect of prohibiting a physician from referring patients to physical therapy services owned by the physician and provided in the physician's office;

(D) examine the delivery of physical therapists' services within the facilities of Department of Defense; and

(E) analyze the potential impact on medicare beneficiaries and on expenditures under the medicare program of eliminating the need for a physician referral and physician certification for physical therapist services under the medicare program.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date of the enactment of this Act.

SEC. 514. ACCELERATED IMPLEMENTATION OF 20 PERCENT COINSURANCE FOR HOSPITAL OUTPATIENT DEPARTMENT (OPD) SERVICES; OTHER OPD PROVISIONS.

(a) ACCELERATED IMPLEMENTATION OF COINSURANCE REDUCTIONS.—Section 1833(t)(8)(C)(ii) (42 U.S.C. 1395l(t)(8)(C)(ii)) is amended by striking subclauses (III) through (V) and inserting the following:

"(III) For procedures performed in 2004, 45 percent.

"(IV) For procedures performed in 2005, 40 percent.

''(V) For procedures performed in 2006, 2007, 2008 and 2009, 35 percent.

''(VI) For procedures performed in 2010, 30 percent.

''(VII) For procedures performed in 2011, 25 percent.

''(VIII) For procedures performed in 2012 and thereafter, 20 percent.''.

(b) TREATMENT OF TEMPERATURE MONITORED CRYOABLATION.—

(1) IN GENERAL.—Section 1833(t)(6)(A)(ii) (42 U.S.C. 1395l(t)(6)(A)(ii)) is amended by striking ''or temperature monitored cryoablation''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) applies to payment for services furnished on or after January 1, 2003.

SEC. 515. COVERAGE OF AN INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), is amended—

(1) in subparagraph (U), by striking ''and'' at the end;

(2) in subparagraph (V), by inserting ''and'' at the end; and

(3) by adding at the end the following new subparagraph:

''(W) an initial preventive physical examination (as defined in subsection (ww));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''Initial Preventive Physical Examination

''(ww) The term 'initial preventive physical examination' means physicians' services consisting of a physical examination with the goal of health promotion and disease detection and includes items and services specified by the Secretary in regulations.''.

(c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

(1) DEDUCTIBLE.—The first sentence of section 1833(b) (42 U.S.C. 1395l(b)) is amended—

(A) by striking ''and'' before ''(6)'', and

(B) by inserting before the period at the end the following: '', and (7) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww))''.

(2) COINSURANCE.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended—

(A) in clause (N), by inserting ''(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))'' after ''80 percent''; and

(B) in clause (O), by inserting ''(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))'' after ''80 percent''.

(d) PAYMENT AS PHYSICIANS' SERVICES.—Section 1848(j)(3) (42 U.S.C. 1395w–4(j)(3)) is amended by inserting ''(2)(W),'' after ''(2)(S),''.

(e) OTHER CONFORMING AMENDMENTS.—Section 1862(a) (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (1)—

(A) by striking ''and'' at the end of subparagraph (H);

(B) by striking the semicolon at the end of subparagraph (I) and inserting '', and''; and

(C) by adding at the end the following new subparagraph:

''(J) in the case of an initial preventive physical examination, which is performed not later than 6 months after the date the individual's first coverage period begins under part B;''; and

(2) in paragraph (7), by striking ''or (H)'' and inserting ''(H), or (J)''.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2004, but only for individuals whose coverage period begins on or after such date.

SEC. 516. RENAL DIALYSIS SERVICES.

(a) REPORT ON DIFFERENCES IN COSTS IN DIFFERENT SETTINGS.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report containing—

(1) an analysis of the differences in costs of providing renal dialysis services under the medicare program in home settings and in facility settings;

(2) an assessment of the percentage of overhead costs in home settings and in facility settings; and

(3) an evaluation of whether the charges for home dialysis supplies and equipment are reasonable and necessary.

(b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDIATRIC FACILITIES.—

(1) IN GENERAL.—Section 422(a)(2) of BIPA is amended—

(A) in subparagraph (A), by striking ''and (C)'' and inserting '', (C), and (D)'';

(B) in subparagraph (B), by striking ''In the case'' and inserting ''Subject to subparagraph (D), in the case''; and

(C) by adding at the end the following new subparagraph:

''(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term 'pediatric facility' means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.''.

(2) CONFORMING AMENDMENT.—The fourth sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)) is amended by striking ''The Secretary'' and inserting ''Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Secretary''.

(c) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR SERVICES FURNISHED IN 2004.—Notwithstanding any other provision of law, with respect to payment under part B of title XVIII of the Social Security Act for renal dialysis services furnished in 2004, the composite payment rate otherwise established under section 1881(b)(7) of such Act (42 U.S.C. 1395rr(b)(7)) shall be increased by 1.2 percent.

SEC. 517. IMPROVED PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES.

(a) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by inserting before the period at the end the following: ''and does not include screening mammography (as defined in section 1861(jj)) and unilateral and bilateral diagnostic mammography''.

(b) ADJUSTMENT TO TECHNICAL COMPONENT.—For diagnostic mammography performed on or after January 1, 2004, for which payment is made under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4), the Secretary, based on the most recent cost data available, shall provide for an appropriate adjustment in the payment amount for the technical component of the diagnostic mammography.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to mammography performed on or after January 1, 2004.

SEC. 518. WAIVER OF PART B LATE ENROLLMENT PENALTY FOR CERTAIN MILITARY RETIREES; SPECIAL ENROLLMENT PERIOD.

(a) WAIVER OF PENALTY.—

(1) IN GENERAL.—Section 1839(b) (42 U.S.C. 1395r(b)) is amended by adding at the end the following new sentence: ''No increase in the premium shall be effected for a month in the case of an individual who is 65 years of age or older, who enrolls under this part during 2001, 2002, or 2003, and who demonstrates to the Secretary before December 31, 2003, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to premiums for months beginning with January 2003. The Secretary of Health and Human Services shall establish a method for providing rebates of premium penalties paid for months on or after January 2003 for which a penalty does not apply under such amendment but for which a penalty was previously collected.

(b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

(1) IN GENERAL.—In the case of any individual who, as of the date of the enactment of this Act, is 65 years of age or older, is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act, and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary of Health and Human Services shall provide for a special enrollment period during which the individual may enroll under such part. Such period shall begin as soon as possible after the date of the enactment of this Act and shall end on December 31, 2003.

(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act shall begin on the

first day of the month following the month in which the individual enrolls.

SEC. 519. COVERAGE OF CHOLESTEROL AND BLOOD LIPID SCREENING.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 515(a), is amended—

(1) in subparagraph (V), by striking ''and'' at the end;

(2) in subparagraph (W), by inserting ''and'' at the end; and

(3) by adding at the end the following new subparagraph:

''(X) cholesterol and other blood lipid screening tests (as defined in subsection (xx));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x), as amended by section 515(b), is amended by adding at the end the following new subsection:

''Cholesterol and Other Blood Lipid Screening Test

''(xx)(1) The term 'cholesterol and other blood lipid screening test' means diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels.

''(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency and type of cholesterol and other blood lipid screening tests, except that such frequency may not be more often than once every 2 years.''.

(c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by section 515(e), is amended

(1) by striking ''and'' at the end of subparagraph (I);

(2) by striking the semicolon at the end of subparagraph (J) and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(K) in the case of a cholesterol and other blood lipid screening test (as defined in section 1861(xx)(1)), which is performed more frequently than is covered under section 1861(xx)(2).''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2004.

TITLE VI—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

SEC. 601. ELIMINATION OF 15 PERCENT REDUCTION IN PAYMENT RATES UNDER THE PROSPECTIVE PAYMENT SYSTEM.

(a) IN GENERAL.—Section 1895(b)(3)(A) (42 U.S.C. 1395fff(b)(3)(A)) is amended to read as follows:

"(A) INITIAL BASIS.—Under such system the Secretary shall provide for computation of a standard prospective payment amount (or amounts) as follows:

"(i) Such amount (or amounts) shall initially be based on the most current audited cost report data available to the Secretary and shall be computed in a manner so that the total amounts payable under the system for fiscal year 2001 shall be equal to the total amount that would have been made if the system had not been in effect and if section 1861(v)(1)(L)(ix) had not been enacted.

"(ii) For fiscal year 2002 and for the first quarter of fiscal year 2003, such amount (or amounts) shall be equal to the amount (or amounts) determined under this paragraph for the previous fiscal year, updated under subparagraph (B).

"(iii) For 2003, such amount (or amounts) shall be equal to the amount (or amounts) determined under this paragraph for fiscal year 2002, updated under subparagraph (B) for 2003.

"(iv) For 2004 and each subsequent year, such amount (or amounts) shall be equal to the amount (or amounts) determined under this paragraph for the previous year, updated under subparagraph (B).

Each such amount shall be standardized in a manner that eliminates the effect of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner consistent with the case mix and wage level adjustments provided under paragraph (4)(A). Under the system, the Secretary may recognize regional differences or differences based upon whether or not the services or agency are in an urbanized area.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the amendments made by section 501 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (as enacted into law by section 1(a)(6) of Public Law 106–554).

SEC. 602. UPDATE IN HOME HEALTH SERVICES.

(a) CHANGE TO CALENDAR YEAR UPDATE.—

(1) IN GENERAL.—Section 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended—

(A) in paragraph (3)(B)(i)—

(i) by striking ''each fiscal year (beginning with fiscal year 2002)'' and inserting ''fiscal year 2002 and for each subsequent year (beginning with 2003)''; and

(ii) by inserting ''or year'' after ''the fiscal year'';

(B) in paragraph (3)(B)(ii)—

(i) in subclause (II), by striking ''fiscal year'' and inserting ''year'' and by redesignating such subclause as subclause (III); and

(ii) in subclause (I), by striking ''each of fiscal years 2002 and 2003'' and inserting the following: ''fiscal year 2002, the home health market basket percentage increase (as defined in clause (iii)) minus 1.1 percentage points;

''(II) 2003'';

(C) in paragraph (3)(B)(iii), by inserting ''or year'' after ''fiscal year'' each place it appears;

(D) in paragraph (3)(B)(iv)—

(i) by inserting ''or year'' after ''fiscal year'' each place it appears; and

(ii) by inserting ''or years'' after ''fiscal years''; and

(E) in paragraph (5), by inserting ''or year'' after ''fiscal year''.

(2) TRANSITION RULE.—The standard prospective payment amount (or amounts) under section 1895(b)(3) of the Social Security Act for the calendar quarter beginning on October 1, 2002, shall be such amount (or amounts) for the previous calendar quarter.

(b) CHANGES IN UPDATES FOR 2003, 2004, AND 2005.—Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(1)(B), is amended—

(1) in subclause (II), by striking ''the home health market basket percentage increase (as defined in clause (iii)) minus 1.1 percentage points'' and inserting ''2.0 percentage points'';

(2) by striking ''or'' at the end of subclause (II);

(3) by redesignating subclause (III) as subclause (V); and

(4) by inserting after subclause (II) the following new subclause:

''(III) 2004, 1.1 percentage points;

''(IV) 2005, 2.7 percentage points; or''.

(c) PAYMENT ADJUSTMENT.—

(1) IN GENERAL.—Section 1895(b)(5) (42 U.S.C. 1395fff(b)(5)) is amended by striking ''5 percent'' and inserting ''3 percent''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to years beginning with 2003.

SEC. 603. OASIS TASK FORCE; SUSPENSION OF CERTAIN OASIS DATA COLLECTION REQUIREMENTS PENDING TASK FORCE SUBMITTAL OF REPORT.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish and appoint a task force (to be known as the ''OASIS Task Force'') to examine the data collection and reporting requirements under OASIS. For purposes of this section, the term ''OASIS'' means the Outcome and Assessment Information Set required by reason of section 4602(e) of Balanced Budget Act of 1997 (42 U.S.C. 1395fff note).

(b) COMPOSITION.—The OASIS Task Force shall be composed of the following:

(1) Staff of the Centers for Medicare & Medicaid Services with expertise in post-acute care.

(2) Representatives of home health agencies.

(3) Health care professionals and research and health care quality experts outside the Federal Government with expertise in post-acute care.

(4) Advocates for individuals requiring home health services.

(c) DUTIES.—

(1) REVIEW AND RECOMMENDATIONS.—The OASIS Task Force shall review and make recommendations to the Secretary regarding changes in OASIS to improve and simplify data collection for purposes of—

(A) assessing the quality of home health services; and

(B) providing consistency in classification of patients into home health resource groups (HHRGs) for payment under section 1895 of the Social Security Act (42 U.S.C. 1395fff).

(2) SPECIFIC ITEMS.—In conducting the review under paragraph (1), the OASIS Task Force shall specifically examine—

(A) the 41 outcome measures currently in use;

(B) the timing and frequency of data collection; and

(C) the collection of information on comorbidities and clinical indicators.

(3) REPORT.—The OASIS Task Force shall submit a report to the Secretary containing its findings and recommendations for changes in OASIS by not later than 18 months after the date of the enactment of this Act.

(d) SUNSET.—The OASIS Task Force shall terminate 60 days after the date on which the report is submitted under subsection (c)(2).

(e) NONAPPLICATION OF FACA.—The provisions of the Federal Advisory Committee Act shall not apply to the OASIS Task Force.

(f) SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS PENDING TASK FORCE REPORT.—

(1) IN GENERAL.—During the period described in paragraph (2), the Secretary of Health and Human Services may not require, under section 4602(e) of the Balanced Budget Act of 1997 or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act.

(2) PERIOD OF SUSPENSION.—The period described in this paragraph—

(A) begins on January 1, 2003, and

(B) ends on the last day of the 2nd month beginning after the date the report is submitted under subsection (c)(2).

SEC. 604. MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff).

Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study under subsection (a).

Subtitle B—Direct Graduate Medical Education

SEC. 611. REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.

(a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C. 1395ww(h)(4)) is amended—

(1) in subparagraph (F)(i), by inserting ''subject to subparagraph (I),'' after ''October 1, 1997,'';

(2) in subparagraph (H)(i), by inserting ''subject to subparagraph (I),'' after ''subparagraphs (F) and (G),''; and

(3) by adding at the end the following new subparagraph:

''(I) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

''(i) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

''(I) IN GENERAL.—If a hospital's resident level (as defined in clause (iii)(I)) is less than the otherwise applicable resident limit (as defined in clause (iii)(II)) for each of the reference periods (as defined in subclause (II)), effective for cost reporting periods beginning on or after January 1, 2003, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such limit and the reference resident level specified in subclause (III) (or subclause (IV) if applicable).

"(II) REFERENCE PERIODS DEFINED.—In this clause, the term 'reference periods' means, for a hospital, the 3 most recent consecutive cost reporting periods of the hospital for which cost reports have been settled (or, if not, submitted) on or before September 30, 2001.

"(III) REFERENCE RESIDENT LEVEL.—Subject to subclause (IV), the reference resident level specified in this subclause for a hospital is the highest resident level for the hospital during any of the reference periods.

"(IV) ADJUSTMENT PROCESS.—Upon the timely request of a hospital, the Secretary may adjust the reference resident level for a hospital to be the resident level for the hospital for the cost reporting period that includes July 1, 2002.

"(ii) REDISTRIBUTION.—

"(I) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limits for hospitals by an aggregate number estimated by the Secretary that does not exceed the aggregate reduction in such limits attributable to clause (i) (without taking into account any adjustment under subclause (IV) of such clause).

"(II) EFFECTIVE DATE.—No increase under subclause (I) shall be permitted or taken into account for a hospital for any portion of a cost reporting period that occurs before July 1, 2003, or before the date of the hospital's application for an increase under this clause. No such increase shall be permitted for a hospital unless the hospital has applied to the Secretary for such increase by December 31, 2004.

"(III) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the

increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall take into account the need for such an increase by specialty and location involved, consistent with subclause (IV).

"(IV) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall first distribute the increase to programs of hospitals located in rural areas or in urban areas that are not large urban areas (as defined for purposes of subsection (d)) on a first-come-first-served basis (as determined by the Secretary) based on a demonstration that the hospital will fill the positions made available under this clause and not to exceed an increase of 25 full-time equivalent positions with respect to any hospital.

"(V) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this clause, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital.

"(VI) CONSTRUCTION.—Nothing in this clause shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6) or as affecting the ability of a hospital to establish new medical residency training programs under subparagraph (H).

"(iii) RESIDENT LEVEL AND LIMIT DEFINED.—In this subparagraph:

"(I) RESIDENT LEVEL.—The term 'resident level' means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under this paragraph), in the fields of allopathic and osteopathic medicine for the hospital.

"(II) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) on the resident level for the hospital determined without regard to this subparagraph.".

(b) NO APPLICATION OF INCREASE TO IME.—Section 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended by adding at the end the following: "The provisions of clause (i) of subparagraph (I) of subsection (h)(4) shall apply with respect to the first sentence of this clause in the same manner as it applies with respect to subparagraph (F) of such subsection, but the provisions of clause (ii) of such subparagraph shall not apply.".

(c) REPORT ON EXTENSION OF APPLICATIONS UNDER REDISTRIBUTION PROGRAM.—Not later than July 1, 2004, the Secretary shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident limits under section 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by subsection (a)).

SEC. 612. INCREASING FOR 5 YEARS TO 100 PERCENT OF THE LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT THE PAYMENT FLOOR FOR DIRECT GRADUATE MEDICAL EDUCATION PAYMENTS UNDER THE MEDICARE PROGRAM.

Section 1886(h)(2)(D)(iii) (42 U.S.C. 1395ww(h)(2)(D)(iii)), as amended by section 511 of BIPA, is amended—

(1) by striking ''and'' after ''70 percent,''; and

(2) by inserting after ''85 percent,'' the following: ''and for cost reporting periods beginning during the period beginning on October 1, 2002, and ending on September 31, 2007, shall not be less than 100 percent,''.

Subtitle C—Other Provisions

SEC. 621. MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXAMINATION OF BUDGET CONSEQUENCES.—Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the end the following new paragraph:

''(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.''.

(b) CONSIDERATION OF EFFICIENT PROVISION OF SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–6(b)(2)(B)(i)) is amended by inserting ''the efficient provision of'' after ''expenditures for''.

(c) ADDITIONAL REPORTS.—

(1) DATA NEEDS AND SOURCES.—The Medicare Payment Advisory Commission shall conduct a study, and submit a report to Congress by not later than June 1, 2003, on the need for current data, and sources of current data available, to determine the solvency and financial circumstances of hospitals and other medicare providers of services. The Commission shall examine data on uncompen-

sated care, as well as the sahre of uncompensated care accounted for by the expenses for treating illegal aliens.

(2) USE OF TAX-RELATED RETURNS.—Using return information provided under Form 990 of the Internal Revenue Service, the Commission shall submit to Congress, by not later than June 1, 2003, a report on the following:

(A) Investments and capital financing of hospitals participating under the medicare program and related foundations.

(B) Access to capital financing for private and for not-for-profit hospitals.

SEC. 622. DEMONSTRATION PROJECT FOR DISEASE MANAGEMENT FOR CERTAIN MEDICARE BENEFICIARIES WITH DIABETES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a demonstration project under this section (in this section referred to as the ''project'') to demonstrate the impact on costs and health outcomes of applying disease management to certain medicare beneficiaries with diagnosed diabetes. In no case may the number of participants in the project exceed 30,000 at any time.

(b) VOLUNTARY PARTICIPATION.—

(1) ELIGIBILITY.—Medicare beneficiaries are eligible to participate in the project only if—

(a) they are Hispanic, as determined by the Secretary;

(A) they meet specific medical criteria demonstrating the appropriate diagnosis and the advanced nature of their disease;

(B) their physicians approve of participation in the project; and

(C) they are not enrolled in a Medicare+Choice plan.

(2) BENEFITS.—A medicare beneficiary who is enrolled in the project shall be eligible—

(A) for disease management services related to their diabetes; and

(B) for payment for all costs for prescription drugs without regard to whether or not they relate to the diabetes, except that the project may provide for modest cost-sharing with respect to prescription drug coverage.

(c) CONTRACTS WITH DISEASE MANAGEMENT ORGANIZATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall carry out the project through contracts with up to three disease management organizations. The Secretary shall not enter into such a contract with an organization unless the organization demonstrates that it can produce improved health outcomes and reduce aggregate medicare expenditures consistent with paragraph (2).

(2) CONTRACT PROVISIONS.—Under such contracts—

(A) such an organization shall be required to provide for prescription drug coverage described in subsection (b)(2)(B);

(B) such an organization shall be paid a fee negotiated and established by the Secretary in a manner so that (taking into account savings in expenditures under parts A and B of the medicare program under title XVIII of the Social Security Act) there will be no net increase, and to the extent practicable, there will be a net reduction in expenditures under the medicare program as a result of the project; and

(C) such an organization shall guarantee, through an appropriate arrangement with a reinsurance company or otherwise, the prohibition on net increases in expenditures described in subparagraph (B).

(3) PAYMENTS.—Payments to such organizations shall be made in appropriate proportion from the Trust Funds established under title XVIII of the Social Security Act.

(4) WORKING GROUP.—The Secretary shall establish within the Department of Health and Human Services a working group consisting of employees of the Department to carry out the following:

(A) To oversee the project.

(B) To establish policy and criteria for medicare disease management programs within the Department, including the establishment of policy and criteria for such programs.

(C) To identify targeted medical conditions and targeted individuals.

(D) To select areas in which such programs are carried out.

(E) To monitor health outcomes under such programs.

(F) To measure the effectiveness of such programs in meeting any budget neutrality requirements.

(G) Otherwise to serve as a central focal point within the Department for dissemination of information on medicare disease management programs.

(d) APPLICATION OF MEDIGAP PROTECTIONS TO DEMONSTRATION PROJECT ENROLLEES.—(1) Subject to paragraph (2), the provisions of section 1882(s)(3) (other than clauses (i) through (iv) of subparagraph (B)) and 1882(s)(4) of the Social Security Act shall apply to enrollment (and termination of enrollment) in the demonstration project under this section, in the same manner as they apply to enrollment (and termination of enrollment) with a Medicare+Choice organization in a Medicare+Choice plan.

(2) In applying paragraph (1)—

(A) any reference in clause (v) or (vi) of section 1882(s)(3)(B) of such Act to 12 months is deemed a reference to the period of the demonstration project; and

(B) the notification required under section 1882(s)(3)(D) of such Act shall be provided in a manner specified by the Secretary of Health and Human Services.

(e) DURATION.—The project shall last for not longer than 3 years.

(f) WAIVER.—The Secretary of Health and Human Services shall waive such provisions of title XVIII of the Social Se-

curity Act as may be necessary to provide for payment for services under the project in accordance with subsection (c)(3).

(g) REPORT.—The Secretary of Health and Human Services shall submit to Congress an interim report on the project not later than 2 years after the date it is first implemented and a final report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on costs and health outcomes and recommendations on the cost-effectiveness of extending or expanding the project.

(h) GAO STUDY ON DISEASE MANAGEMENT PROGRAMS.—The Comptroller General of the United States shall conduct a study that compares disease management programs under title XVIII of the Social Security Act with such programs conducted in the private sector, including the prevalence of such programs and programs for case management. The study shall identify the cost-effectiveness of such programs and any savings achieved by such programs. The Comptroller General shall submit a report on such study to Congress by not later than 18 months after the date of the enactment of this Act.

SEC. 623. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary of Health and Human Services shall establish a demonstration project (in this section referred to as the ''demonstration project'') under which the Secretary shall, as part of a plan of an episode of care for home health services established for a medicare beneficiary, permit a medical adult day care facility or a home health agency, directly or under arrangements with a medical adult day care facility, to provide medical adult day care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(b) PAYMENT.—

(1) IN GENERAL.—The amount of payment for an episode of care for home health services, a portion of which

consists of substitute medical adult day care services, under the demonstration project shall be made at a rate equal to 95 percent of the amount that would otherwise apply for such home health services under section 1895 of the Social Security Act (42 u.s.c. 1395fff). In no case may a a medical adult day care facility or home health agency, or a medical adult day care facility under arrangements with a home health agency, separately charge a beneficiary for medical adult day care services furnished under the plan of care.

(2) BUDGET NEUTRALITY FOR DEMONSTRATION PROJECT.—Notwithstanding any other provision of law, the Secretary shall provide for an appropriate reduction in the aggregate amount of additional payments made under section 1895 of the Social Security Act (42 U.S.C. 1395fff) to reflect any increase in amounts expended from the Trust Funds as a result of the demonstration project conducted under this section.

(c) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in not more than 5 sites in States selected by the Secretary that license or certify providers of services that furnish medical adult day care services.

(d) DURATION.—The Secretary shall conduct the demonstration project for a period of 3 years.

(e) VOLUNTARY PARTICIPATION.—Participation of medicare beneficiaries in the demonstration project shall be voluntary. The total number of such beneficiaries that may participate in the project at any given time may not exceed 15,000.

(f) PREFERENCE IN SELECTING AGENCIES.—In selecting medical adult day care facilities and home health agencies to participate under the demonstration project, the Secretary shall give preference to those facilities and agencies that—

(1) are currently licensed or certified to furnish medical adult day care services; and

(2) have furnished medical adult day care services to medicare beneficiaries for a continuous 2-year period before the beginning of the demonstration project.

(g) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as may be necessary for the purposes of carrying out the demonstration project, other than waiving the requirement that an individual be homebound in order to be eligible for benefits for home health services.

(h) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the clinical and cost effectiveness of the demonstration project. Not later 30 months after the commencement of the project, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

(1) An analysis of the patient outcomes and costs of furnishing care to the medicare beneficiaries participating in the project as compared to such outcomes and costs to beneficiaries receiving only home health services for the same health conditions.

(2) Such recommendations regarding the extension, expansion, or termination of the project as the Secretary determines appropriate.

(i) DEFINITIONS.—In this section:

(1) HOME HEALTH AGENCY.—The term ''home health agency'' has the meaning given such term in section 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

(2) MEDICAL ADULT DAY CARE FACILITY.—The term ''medical adult day care facility'' means a facility that—

(A) has been licensed or certified by a State to furnish medical adult day care services in the State for a continuous 2-year period;

(B) is engaged in providing skilled nursing services and other therapeutic services directly or under arrangement with a home health agency;

(C) meets such standards established by the Secretary to assure quality of care and such other require-

ments as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility; and

(D) provides medical adult day care services.

(3) MEDICAL ADULT DAY CARE SERVICES.—The term ''medical adult day care services'' means—

(A) home health service items and services described in paragraphs (1) through (7) of section 1861(m) furnished in a medical adult day care facility;

(B) a program of supervised activities furnished in a group setting in the facility that—

(i) meet such criteria as the Secretary determines appropriate; and

(ii) is designed to promote physical and mental health of the individuals; and

(C) such other services as the Secretary may specify.

(4) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual entitled to benefits under part A of this title, enrolled under part B of this title, or both.

SEC. 624. PUBLICATION ON FINAL WRITTEN GUIDANCE CONCERNING PROHIBITIONS AGAINST DISCRIMINATION BY NATIONAL ORIGIN WITH RESPECT TO HEALTH CARE SERVICES.

Not later than January 1, 2003, the Secretary shall issue final written guidance concerning the application of the prohibition in title VI of the Civil Rights Act of 1964 against national origin discrimination as it affects persons with limited English proficiency with respect to access to health care services under the medicare program.

TITLE VII—MEDICAID AND OTHER HEALTH PROVISIONS

Subtitle A—Medicaid Provisions

SEC. 701. DSH PROVISIONS.

(a) CONTINUATION OF MEDICAID DSH ALLOTMENT ADJUSTMENTS UNDER BIPA2000.—

(1) IN GENERAL.—Section 1923(f) (42 U.S.C. 1396r–4(f))—

(A) in paragraph (2)—

(i) in the heading, by striking ''THROUGH 2002'' and inserting ''THROUGH 2000'';

(ii) by striking ''ending with fiscal year 2002'' and inserting ''ending with fiscal year 2000''; and

(iii) in the table in such paragraph, by striking the columns labeled ''FY 01'' and ''FY02'';

(B) in paragraph (3)(A), by striking ''paragraph (2)'' and inserting ''paragraph (4)''; and

(C) in paragraph (4), as added by section 701(a)(1) of BIPA—

(i) by striking ''FOR FISCAL YEARS 2001 AND 2002'' in the heading;

(ii) in subparagraph (A), by striking ''Notwithstanding paragraph (2), the'' and inserting ''The'';

(iii) in subparagraph (C)—

(I) by striking ''NO APPLICATION'' and inserting ''APPLICATION''; and

(II) by striking ''without regard to'' and inserting ''taking into account''.

(2) INCREASE IN MEDICAID DSH ALLOTMENT FOR THE DISTRICT OF COLUMBIA.—

(A) IN GENERAL.—Effective for DSH allotments beginning with fiscal year 2002, the item in the table contained in section 1923(f)(2) of the Social Security Act (42 U.S.C. 1396r–4(f)(2)) for the District of Columbia for the DSH allotment for FY 00 (fiscal year 2000) is amended by striking ''32'' and inserting ''49''.

(B) CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as preventing the application of section 1923(f)(4) of the Social Security Act (as amended by subsection (a)) to the District of Columbia for fiscal year 2002 and subsequent fiscal years.

(b) INCREASE IN FLOOR FOR TREATMENT AS AN EXTREMELY LOW DSH STATE TO 3 PERCENT IN FISCAL YEAR 2002.—

(1) INCREASE IN DSH FLOOR.—Section 1923(f)(5) (42 U.S.C. 1396r–4(f)(5)) is amended—

(A) by striking ''fiscal year 1999'' and inserting ''fiscal year 2001'';

(B) by striking ''August 31, 2000'' and inserting ''August 31, 2002'';

(C) by striking ''1 percent'' each place it appears and inserting ''3 percent''; and

(D) by striking ''fiscal year 2001'' and inserting ''fiscal year 2003''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) take effect on October 1, 2002, and apply to DSH allotments under title XIX of the Social Security Act for fiscal year 2003 and each fiscal year thereafter.

SEC. 702. 1-YEAR EXTENSION OF Q–I1 PROGRAM.

Section 1902(a)(10)(E)(E)(iv) (42 U.S.C. 1396a(a)(10)(E)(E)(iv)) is amended by striking ''2002'' and inserting ''2003''.

Subtitle B—Internet Pharmacies

SEC. 711. INTERNET SALES OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter 5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following section:

''SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.

''(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

''(1) IN GENERAL.—A person may not dispense a prescription drug pursuant to a sale of the drug by such person if—

''(A) the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sales transaction for the drug, through an Internet site; and

"(B) such site, or any other Internet site used by such person for purposes of sales of a prescription drug, fails to meet each of the requirements specified in paragraph (2) (other than a site or pages on a site that are not intended to be accessed by purchasers or prospective purchasers).

"(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (B) of paragraph (1) for a person to whom such paragraph applies are as follows:

"(A) Each page of the site shall include either the following information or a link to a page that provides the following information:

"(i) The name of such person; the address of the principal place of business of the person with respect to sales of prescription drugs through the Internet; and the telephone number for such place of business.

"(ii) Each State in which the person is authorized by law to dispense prescription drugs.

"(iii) The name of each individual who serves as a pharmacist for purposes of the site, and each State in which the individual is authorized by law to dispense prescription drugs.

"(iv) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations; and the type or types of health professions for which the individual holds such licenses or other authorizations.

"(B) A link to which paragraph (1) applies shall be clearly visible on the page involved, shall not be of a size smaller than other links on the page (if any),

and shall include in the caption for the link the words 'licensing and contact information'.

"(b) INTERNET SALES WITHOUT APPROPRIATE MEDICAL RELATIONSHIPS.—

"(1) IN GENERAL.—A person may not dispense a prescription drug, or arrange the dispensing of such a drug, pursuant to a sale of the drug if—

"(A) for purposes of such sale, the purchaser communicated with the person through the Internet;

"(B) the patient for whom the drug was purchased did not, when such communications began, have a prescription for the drug;

"(C) pursuant to such communications, the person provided for the involvement of a practitioner and the practitioner issued a prescription for the drug that was purchased;

"(D) the person knew, or had reason to know, that the practitioner did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

"(E)(i) the person received payment for the drug from the purchaser; or

"(ii) in the case of arranging the dispensing of the drug, the person received payment for doing so from the person who dispensed the drug.

For purposes of subparagraph (E), payment is received if money or other valuable consideration is received.

"(2) QUALIFYING MEDICAL RELATIONSHIP.—

"(A) IN GENERAL.—With respect to issuing a prescription for a drug for a patient, a practitioner has a qualifying medical relationship with the patient for purposes of this section if at least one in-person medical evaluation of the patient has been conducted by the practitioner. This subparagraph and subparagraph (B) may not be construed as having any applicability beyond this section.

"(B) IN-PERSON MEDICAL EVALUATION.—A medical evaluation by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to whether portions of the evaluation are conducted by other health professionals.

"(c) ACTIONS BY STATES.—

"(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(l), the State may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

"(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

"(A) to intervene in such action;

"(B) upon so intervening, to be heard on all matters arising therein; and

"(C) to file petitions for appeal.

"(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising

the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

''(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

''(5) ACTIONS BY OTHER STATE OFFICIALS.—

''(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

''(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

''(d) DEFINITIONS.—

''(1) INTERNET-RELATED DEFINITIONS.—For purposes of this section:

''(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

''(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site

for the purpose of serving, when activated, as a method for executing an electronic command—

"(i) to move from viewing one portion of a page on such site to another portion of the page;

"(ii) to move from viewing one page on such site to another page on such site; or

"(iii) to move from viewing a page on one Internet site to a page on another Internet site.

"(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

"(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

"(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

"(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

"(2) OTHER DEFINITIONS.—For purposes of this section:

"(A) The term 'practitioner', with respect to the issuance of a prescription for a drug for a patient, means—

"(i) an individual authorized by law to administer the drug; or

"(ii) an individual who is not so authorized but represents himself or herself as an individual who is so authorized.

"(B) The term 'prescription drug' means a drug that is subject to section 503(b).

''(C) The term 'qualifying medical relationship', with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).''.

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (k) the following:

''(l) The dispensing of a prescription drug in violation of section 503B, or arranging for the dispensing of such a drug in violation of such section.''.

SEC. 712. INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.

In carrying out section 503B of the Federal Food, Drug, and Cosmetic Act (as added by section 711 of this Act), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

SEC. 713. EFFECTIVE DATE.

The amendments made by section 711 take effect upon the expiration of the 60-day period beginning on the date of the enactment of this Act, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cosmetic Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

Subtitle C—Treatment of Rare Diseases

SEC. 721. NIH OFFICE OF RARE DISEASES AT NATIONAL INSTITUTES OF HEALTH.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by Public Law 107–84, is amended by inserting after section 404E the following:

''OFFICE OF RARE DISEASES

''SEC. 404F. (a) ESTABLISHMENT.—There is established within the Office of the Director of NIH an office to be known as the Office of Rare Diseases (in this section referred to as the 'Office'), which shall be headed by a Director (in this section referred to as the 'Director'), appointed by the Director of NIH.

''(b) DUTIES.—

''(1) IN GENERAL.—The Director of the Office shall carry out the following:

''(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

''(B) The Director shall, with respect to rare diseases, promote coordination and cooperation among the national research institutes and centers and entities whose research is supported by such institutes.

''(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 404G.

''(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

''(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

"(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies particular projects or types of projects that should in the future be conducted or supported by the national research institutes and centers or other entities in the field of research on rare diseases.

"(G) The Director shall prepare the NIH Director's annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.

"(2) PRINCIPAL ADVISOR REGARDING ORPHAN DISEASES.—With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

"(c) DEFINITION.—For purposes of this section, the term 'rare disease' means any disease or condition that affects less than 200,000 persons in the United States.

"(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $4,000,000 for each of the fiscal years 2003 through 2006.".

SEC. 722. RARE DISEASE REGIONAL CENTERS OF EXCELLENCE.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 721, is further amended by inserting after section 404F the following:

"RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

"SEC. 404G. (a) COOPERATIVE AGREEMENTS AND GRANTS.—

"(1) IN GENERAL.—The Director of the Office of Rare Diseases (in this section referred to as the 'Director'), in

collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

''(2) POLICIES.—A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

''(b) COORDINATION WITH OTHER INSTITUTES.—The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

''(c) USES FOR FEDERAL PAYMENTS UNDER COOPERATIVE AGREEMENTS OR GRANTS.—Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

''(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

''(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

''(3) clinical research and demonstration programs.

''(d) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate

technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

''(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $20,000,000 for each of the fiscal years 2003 through 2006.''.

Subtitle D—Other Provisions Relating to Drugs

SEC. 731. GAO STUDY REGARDING DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study for the purpose of determining—

(1) whether and to what extent there have been increases in utilization rates of prescription drugs that are attributable to guidance regarding direct-to-consumer advertising of such drugs that has been issued by the Food and Drug Administration under section 502(n) of the Federal Food, Drug, and Cosmetic Act; and

(2) if so, whether and to what extent such increased utilization rates have resulted in increases in the costs of public or private health plans, health insurance, or other health programs.

(b) CERTAIN DETERMINATIONS.—The study under subsection (a) shall include determinations of the following:

(1) The extent to which advertisements referred to in such subsection have resulted in effective consumer education about the prescription drugs involved, including an understanding of the risks of the drugs relative to the benefits.

(2) The extent of consumer satisfaction with such advertisements.

(3) The extent of physician satisfaction with the advertisements, including determining whether physicians believe that the advertisements interfere with the exercise of

their medical judgment by influencing consumers to prefer advertised drugs over alternative therapies.

(4) The extent to which the advertisements have resulted in increases in health care costs for taxpayers, for employers, or for consumers due to consumer decisions to seek advertised drugs rather than lower-costs alternative therapies.

(5) The extent to which the advertisements have resulted in decreases in health care costs for taxpayers, for employers, or for consumers due to decreased hospitalization rates, fewer physician visits (not related to hospitalization), lower treatment costs, or reduced instances of employee absences to care for family members with diseases or disorders.

(c) REPORT.—Not later than two years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Congress a report providing the findings of the study under subsection (a).

SEC. 732. CERTAIN HEALTH PROFESSIONS PROGRAMS REGARDING PRACTICE OF PHARMACY.

Part E of title VII of the Public Health Service Act (42 U.S.C. 294n et seq.) is amended by adding at the end the following subpart:

"Subpart 3—Pharmacist Workforce Programs

"SEC. 771. PUBLIC SERVICE ANNOUNCEMENTS.

"(a) PUBLIC SERVICE ANNOUNCEMENTS.—

"(1) IN GENERAL.—The Secretary shall develop and issue public service announcements that advertise and promote the pharmacist profession, highlight the advantages and rewards of being a pharmacist, and encourage individuals to enter the pharmacist profession.

"(2) METHOD.—The public service announcements described in subsection (a) shall be broadcast through appropriate media outlets, including television or radio, in a manner intended to reach as wide and diverse an audience as possible.

''(b) STATE AND LOCAL PUBLIC SERVICE ANNOUNCEMENTS.—

''(1) IN GENERAL.—The Secretary shall award grants to entities to support State and local advertising campaigns through appropriate media outlets to promote the pharmacist profession, highlight the advantages and rewards of being a pharmacist, and encourage individuals from disadvantaged backgrounds to enter the pharmacist profession.

''(2) USE OF FUNDS.—An entity that receives a grant under subsection (a) shall use funds received through such grant to acquire local television and radio time, place advertisements in local newspapers, and post information on billboards or on the Internet, in order to—

''(A) advertise and promote the pharmacist profession;

''(B) promote pharmacist education programs;

''(C) inform the public of public assistance regarding such education programs;

''(D) highlight individuals in the community that are presently practicing as pharmacists to recruit new pharmacists; and

''(E) provide any other information to recruit individuals for the pharmacist profession.

''(3) METHOD.—The campaigns described in subsection (a) shall be broadcast on television or radio, placed in newspapers as advertisements, or posted on billboards or the Internet, in a manner intended to reach as wide and diverse an audience as possible.

''SEC. 772. DEMONSTRATION PROJECT.

''(a) IN GENERAL.—The Secretary shall establish a demonstration project to enhance the participation of individuals who are pharmacists in the National Health Service Corps Loan Repayment Program described in section 338B.

''(b) SERVICES.—Services that may be provided by pharmacists pursuant to the demonstration project established under this section include medication therapy management

services to assure that medications are used appropriately by patients, to enhance patients' understanding of the appropriate use of medications, to increase patients' adherence to prescription medication regimens, to reduce the risk of adverse events associated with medications, and to reduce the need for other costly medical services through better management of medication therapy. Such services may include case management, disease management, drug therapy management, patient training and education, counseling, drug therapy problem resolution, medication administration, the provision of special packaging, or other services that enhance the use of prescription medications.

''(c) PROCEDURE.—The Secretary may not provide assistance to an individual under this section unless the individual agrees to comply with all requirements described in sections 338B and 338E.

''(d) LIMITATIONS.—The demonstration project described in this section shall provide for the participation of—

''(1) individuals to provide services in rural and urban areas; and

''(2) enough individuals to allow the Secretary to properly analyze the effectiveness of such project.

''(e) DESIGNATIONS.—The demonstration project described in this section, and any pharmacists who are selected to participate in such project, shall not be considered by the Secretary in the designation of a health professional shortage area under section 332 during fiscal years 2003 through 2005.

''(f) RULE OF CONSTRUCTION.—This section shall not be construed to require any State to participate in the project described in this section.

''(g) REPORT.—The Secretary shall prepare and submit a report on the project to—

''(1) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(2) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the Senate;

''(3) the Committee on Energy and Commerce of the House of Representatives; and

''(4) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the House of Representatives.

''SEC. 773. INFORMATION TECHNOLOGY.

''(a) GRANTS AND CONTRACTS.—The Secretary may make awards of grants or contracts to qualifying schools of pharmacy for the purpose of assisting such schools in acquiring and installing computer-based systems to provide pharmaceutical education. Education provided through such systems may be graduate education, professional education, or continuing education. The computer-based systems may be designed to provide on-site education, or education at remote sites (commonly referred to as distance learning), or both.

''(b) QUALIFYING SCHOOL OF PHARMACY.—For purposes of this section, the term 'qualifying school of pharmacy' means a school of pharmacy (as defined in section 799B) that requires students to serve in a clinical rotation in which pharmacist services are part of the curriculum.

''SEC. 774. AUTHORIZATION OF APPROPRIATIONS.

''For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2006.''.